

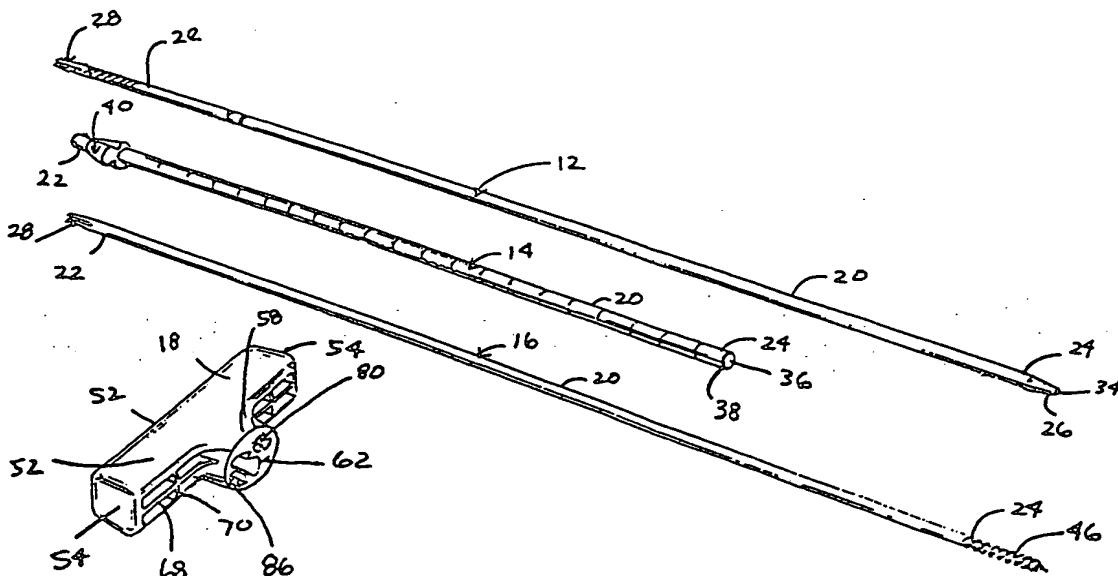
PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 10/00		A1	(11) International Publication Number: WO 99/37212
			(43) International Publication Date: 29 July 1999 (29.07.99)
(21) International Application Number: PCT/US99/01267			(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
(22) International Filing Date: 21 January 1999 (21.01.99)			
(30) Priority Data: 09/014,229 27 January 1998 (27.01.98) US			
(71) Applicant: KYPHON INC. [US/US]; 3110 Coronado Drive, Santa Clara, CA 95054 (US).			
(74) Agents: RYAN, Daniel, D. et al.; 633 West Wisconsin Avenue, Milwaukee, WI 53203 (US).			Published <i>With international search report.</i>

(54) Title: A SLIP-FIT HANDLE FOR HAND-HELD INSTRUMENTS THAT ACCESS INTERIOR BODY REGIONS



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		

- 1 -

**A SLIP-FIT HANDLE FOR HAND-HELD INSTRUMENTS THAT
ACCESS INTERIOR BODY REGIONS**

FIELD OF THE INVENTION

5 The invention generally relates to hand-held surgical instruments and to procedures that deploy these instruments through tissue to access interior regions of the body.

BACKGROUND OF THE INVENTION

10 There are many different types and styles of hand-held surgical instruments that physicians use to gain access into interior body regions. These instruments are intended to penetrate tissue by the application of pushing forces, twisting forces, or both in combination.

15 Often, a single surgical procedure will require the physician to employ different surgical instruments, each possessing a different shape, size, and function. Often, the procedure will require the physician to deploy these instruments in both soft and hard tissue to meet the diagnostic or therapeutic objectives of the procedure. The physician will often need an enhanced mechanical advantage to advance an instrument through tissue, particularly through dense or hard tissue, such as
20 bone.
25

- 2 -

5 The common need to use different instruments in a given procedure, coupled with the absolute need to accurately and reliably deploy each of these different instruments through both soft and hard tissue, often with an enhanced mechanical advantage, complicate the physician's already difficult task. The need to handle different instruments in different ways for different purposes can distract the physician and lead to wasted
10 effort, which lengthen the overall time of the procedure.

SUMMARY OF THE INVENTION

15 The invention provides a handle for releasable attachment to a surgical instrument. The handle permits a physician to fit a selected instrument to the handle tactiley, without need of visual confirmation. At the same time, the handle makes possible the reliable transmission, with increased mechanical advantage, of both torsional
20 and longitudinal loads by the physician to the selected instrument. The handle also permits quick detachment of the selected instrument from the handle, without sticking or inordinate force.

25 In a preferred embodiment, the invention provides a single handle for releasable attachment to one or more different surgical instruments. This aspect of the invention provides a surgical system, which comprises first and second functional instruments and a single mating handle. The first
30 functional instrument includes a first handle attachment site characterized by a first geometry. The second functional instrument includes a second handle attachment site characterized by a second geometry different than the first geometry. The handle is provided for manipulating the first and
35

- 3 -

second functional instruments when in use. The handle includes a first component configured to removably engage the first handle attachment site but not the second handle attachment site. The handle also includes a second component configured to removably engage the second handle attachment site but not the first handle attachment site.

Another aspect of the invention provides a surgical system comprising first and second functional instruments and a handle. The first functional instrument includes a handle attachment site and an interior bore. The second functional instrument is sized for passage through the interior bore of the first functional instrument. The handle has a component configured to removably engage the handle attachment site, for manipulating the first functional instrument when in use. The handle also includes a passageway leading into the component, which allows the second instrument to be passed through the handle and interior bore of the first functional instrument while the first functional instrument is removably engaged by the component.

Still another aspect of the invention provides a surgical procedure kit comprising a functional instrument and a handle including an element to releasably engage the functional instrument for manipulating the functional instruments when in use. The kit also includes an overwrap defining a sealed enclosure holding the functional instrument and handle until use.

In a preferred embodiment, the kit holds selected surgical instruments and auxiliary components required for a given procedure in a secure position during sterilization and storage prior to use. In this embodiment, the handle

- 4 -

releasably attaches to one or more of the surgical instruments contained in the kit. The kit presents the handle, the surgical instruments, and the auxiliary components in an ordered, organized 5 layout, which is arranged to aid the physician in efficiently carrying out the intended procedure, without distraction and wasted effort.

10 Features and advantages of the inventions are set forth in the following Description and Drawings, as well as in the appended Claims.

BRIEF DESCRIPTION OF THE DRAWINGS

15 Fig. 1 is a perspective view of a system including different functional instruments and a T-shaped handle that slip-fits into and out of engagement with the instruments, to aid a physician in manipulating the instruments during use;

20 Fig. 2 is an enlarged perspective view of a first type of tapered flange, carried by at least one of the instruments shown in Fig.1, which slip-fits into and out of the handle;

25 Fig. 3 is an enlarged perspective view of a second type of tapered flange, carried by at least one of the instruments shown in Fig.1, which slip-fits into and out of the handle;

Fig. 4 an end view of the tapered flange shown in Fig. 3, taken generally along line 4-4 in Fig. 3;

30 Fig. 5 is a top view of the T-shaped handle shown in Fig. 1;

Fig. 6 is a side view of the T-shaped handle shown in Fig. 5;

35 Fig. 7 is a bottom view of the T-shaped handle shown in Fig. 5, showing the first and second sockets of the handle;

Fig. 8 is a side perspective view of the

- 5 -

handle shown in Fig. 5, being grasped by a physician and ready for use;

5 Fig. 9 is a perspective view of an obturator instrument having a tapered flange of the type shown in Fig. 2 slip-fitted into the first socket of the handle shown in Figs. 5 to 8, ready for use;

10 Fig. 10 is an enlarged perspective view, with portions broken away, showing the details of the slip fit engagement between the tapered flange and the first handle socket shown in Fig. 9;

15 Fig. 11 is a perspective view of a cannula instrument having a tapered flange of the type shown in Figs. 3 and 4 slip-fitted into the second socket of the handle shown in Figs. 5 to 8, ready for use;

Fig. 12 is an enlarged perspective view, with portions broken away, showing the details of the slip fit engagement between the tapered flange and the second handle socket shown in Fig. 11;

20 Fig. 13 is an enlarged view of the geometries of first and second sockets of the handle shown in Figs. 5 to 8;

25 Fig. 14 is a top view of a kit for storing the one or more functional instruments in association with the handle shown in Figs. 5 to 8 prior to use;

Fig. 15 is an exploded perspective view of the kit shown in Fig. 14;

30 Figs. 16 and 17 are, respectively, top and side views of a human vertebral body;

Fig. 18 is a top view of a vertebral body during insertion of a spinal needle assembly to begin a bone access procedure;

35 Figs. 19 to 21 are top views showing subsequent steps, after insertion of the spinal

- 6 -

needle assembly shown in Fig. 18, of inserting a guide pin component into the vertebral body;

5 Fig. 22 is a perspective view showing a subsequent step, after insertion of the guide pin component shown in Figs. 19 to 21, which uses the handle shown in Figs. 5 to 8 to aid in the deployment of an obturator instrument over the guide pin component;

10 Fig. 23 is a top view of the vertebral body, with the obturator instrument shown in Fig. 22 deployed;

15 Fig. 24 is a perspective view showing a subsequent step, after insertion of the obturator instrument shown in Fig. 22, which uses the handle shown in Figs. 5 to 8 to aid in the deployment of a cannula instrument over the obturator instrument;

Fig. 25 is a top view of the vertebral body, with the cannula instrument shown in Fig. 24 deployed;

20 Fig. 26 is a perspective view showing a subsequent step, after insertion of the cannula instrument shown in Fig. 24, which removes the obturator instrument from the cannula instrument, to leave the cannula instrument and guide pin component in place;

25 Fig. 27 is a top view of the vertebral body, after the obturator removal step shown in Fig. 26, leaving the cannula instrument and guide pin component in place;

30 Fig. 28 is a perspective view showing a subsequent step, after removal of the obturator instrument shown in Fig. 26, which uses the handle shown in Figs. 5 to 8 to aid in the deployment of a drill bit instrument through the cannula instrument along the guide pin component;

- 7 -

Fig. 29 is a top view of the vertebral body, as the drill bit instrument shown in Fig. 28 is deployed with aid of the handle to open a passage into the interior volume of the vertebral body;

5 Fig. 30 is a perspective view showing a subsequent step, after removal of the drill bit instrument and guide pin component shown in Fig. 28, of deploying a catheter instrument carrying a diagnostic or therapeutic element through the cannula instrument into the vertebral body;

10 Fig. 31 is a top view of the vertebral body, as the diagnostic or therapeutic element carried by the catheter component shown in Fig. 30 is deployed into the interior volume of the vertebral body;

15 Fig. 32 is a top view of a round handle, which can be used in association with the functional instruments shown in Fig. 1, in generally the same fashion as the T-shaped handle shown in Figs. 5 to 8;

20 Fig. 33 is a side view of the round handle shown in Fig. 32;

25 Fig. 34 is a bottom view of the round handle shown in Fig. 32, showing the first and second sockets of the handle;

30 Fig. 35 is a perspective view of an elliptical, anvil-style handle, which can be used in association with the functional instruments shown in Fig. 1 when greater tapping or compression force is required to advance an instrument, particularly through hard tissue, like bone;

35 Fig. 36 is a rear side perspective view of the anvil-style handle shown in Fig. 35, showing the first and second sockets of the handle;

Fig. 37 is a rear elevation view of the

- 8 -

anvil-style handle shown in Fig. 35, showing the first and second sockets of the handle;

Fig. 38 is a front elevation view of the anvil-style handle shown in Fig. 35; and

5 Fig. 39 is a perspective view of an alternative system including different functional instruments and a T-shaped handle that slip-fits into and out of engagement with the instruments, to aid a physician in manipulating the instruments
10 during use.

The invention may be embodied in several forms without departing from its spirit or essential characteristics. The scope of the invention is defined in the appended claims, rather than in the
15 specific description preceding them. All embodiments that fall within the meaning and range of equivalency of the claims are therefore intended to be embraced by the claims.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

20 Fig. 1 shows a system 10 for penetrating tissue. The system includes one or more functional instruments 12, 14, and 16 and a handle 18. The handle 18 engages at least one of the functional instruments 12, 14, and 16 in a removable, slip fit
25 fashion to aid a physician in manipulating the instrument 12, 14, or 16 during use.

I. The Instruments

30 The number and type of instruments 12, 14, and 16 can vary. Fig. 1 shows three representative instruments 12, 14, and 16, each having a different size and function.

35 The first, second, and third instruments 12, 14, and 16 share some common features, although they are intended, in use, to perform different functions. The first, second and third instrument

- 9 -

12, 14, and 16 each comprises an elongated, cylindrical body 20 having a proximal end 22 and a distal end 24. The first, second, and third instrument 12, 14, and 16 are each made of a rigid, surgical grade plastic or metal material.

5

A. The Obturator Instrument

The first instrument 12 functions as an obturator. Its distal end 24 is tapered to present a penetrating surface 26. In use, the surface 26 is intended to penetrate soft tissue in response to pushing or twisting forces applied by the physician at the proximal end 22.

10 The proximal end 22 of the obturator instrument 12 presents a flanged surface 28. As also shown in an enlarged view in Fig. 2, the flanged surface 28 tapers from a larger outer diameter to a smaller outer diameter in the direction of the proximal end 22. The flanged surface 28 includes an array of circumferentially spaced teeth 30 with intermediate flutes 32.

15

20 An interior lumen 34 extends through the obturator instrument 12 from the distal end 24 to the proximal end 22. The interior lumen 34 is sized to accommodate a conventional surgical guide pin component to aid in its deployment, as will be described in greater detail later.

25

B. The Cannula Instrument

30 The second instrument 14 functions as a cannula or guide sheath. The cannula instrument 14 is somewhat larger in diameter than and not as long as the obturator instrument 12. As shown in Figs. 1 and 3, the cannula instrument 14 includes an interior lumen 36 that extends from its distal end 24 to its proximal end 22. The interior lumen 36 is 35 sized to accept the obturator instrument 12. The

- 10 -

size of the interior lumen 36 permits a physician to slide and rotate the cannula instrument 14 relative to the obturator instrument 12, and vice versa, as will be described in greater detail later.

5

The distal end 24 of the cannula instrument 14 presents an end surface 38. In use, the end surface 38 of the cannula instrument 14 is intended to penetrate soft tissue surrounding the obturator instrument 12, in response to pushing or twisting

10

forces applied at the proximal end 22.

15

The proximal end 22 carries an enlarged fitting 40. As best shown in an enlarged view in Figs. 3 and 4, the fitting 40 tapers from a larger diameter to a smaller diameter in the direction of the proximal end 22. Like the tapered flange 28 at the proximal end 22 of the obturator instrument 12, the tapered fitting 40 has an array of circumferentially spaced teeth 42 with intermediate flutes 44. The tapered fitting 40 of the cannula instrument 14 possesses a larger maximum outer diameter than the maximum outer diameter of the tapered flange 28 of the obturator instrument 12.

20

C. The Drill Bit Instrument

25

The third instrument 16 functions as a drill bit. The drill bit instrument 16 has generally the same physical dimensions as the obturator instrument 12. Like the obturator instrument 12, the drill bit instrument 16 is intended, in use, to fit for sliding and rotational movement within the interior lumen 36 of the cannula instrument 14.

30

The distal end 24 of the drill bit instrument 16 includes machined cutting edges 46. In use, the cutting edges 46 are intended to penetrate hard tissue in response to rotation and longitudinal load forces applied at the proximal end

35

- 11 -

22 of the drill bit instrument 16.

The proximal end 22 presents a tapered flange 28, substantially identical to the flange 28 on the obturator instrument 12, as Fig. 2 shows in an enlarged view. Like the obturator instrument 12, the tapered flange 28 changes from a larger diameter to a smaller diameter in the direction of the proximal end 22. The tapered flange 28 of the drill bit instrument 16 also includes an array of circumferentially spaced teeth 30 with intermediate flutes 32. The form and orientation of the teeth 30 and flutes 32 on the drill bit instrument 16 correspond to the form and orientation of the teeth 30 and flutes 32 on the obturator instrument 12.

II. The Handle

The handle 18 is made from a molded or cast rigid plastic or metal material. As also shown in Figs. 5 to 8, the handle 18 is shaped to be comfortably and securely grasped by a normal human hand (see Fig. 8). The shape and size to accommodate this function can, of course, vary. In the embodiment shown in Fig. 5, the handle 18 is elongated along a main axis 48 to fit comfortably across the palm of the hand. In a representative embodiment, the handle 18 measures about 76 mm in length along the main axis 48, about 16 mm in width across the main axis 48, and about 25 mm in height normal to the main axis 48. These dimensions can, of course, vary to best serve the intended field of use.

The handle 18 includes a top wall 50, opposed side walls 52, and opposed end walls 54. The junctions 56 of the side walls 52 and end walls 54 with the top wall 50 are preferably rounded according to normal finger joint radii to provide a

- 12 -

comfortable gripping area. The side walls 52 and end walls 54 also taper somewhat outward from the top wall 50 (see Figs. 6 and 8), to enable firm, comfortable grasping between the fingers and thumb, as Fig. 8 shows. The top wall 50 and side walls 52 can be roughened or otherwise textured to provide a secure gripping surfaces. The contours of the handle 18 are also designed to minimize surgical glove tears.

10 The handle 18 includes a center post 58, which is integrally molded to the handle 18 about its geometric center 60 (as Fig. 6 shows). The center post 58 extends downward from the top wall 50 along the geometric center 60 between the side walls 52. The center post 58 has an exposed end surface 62, which terminates below the lower edges 64 of the side and end walls 52 and 54. This gives the handle 18 a general T-shape, when viewed from the side (see Figs. 6 and 8).

20 The underside interior 66 of the handle 18 includes a crossing array of molded stiffening ribs 68 and 70 extending about the center post 58 (as best shown in Fig. 7). Long stiffening ribs 68 extend between the center post 58 and the end walls 54, along the main axis 48 of the handle 18. Cross ribs 70 extend across the long ribs 68 between the side walls 52. The ribs 68 and 70 provide the handle 18 with structural rigidity and strength to transmit, without failure, both longitudinal and 30 torsional load forces.

25 The handle 18 includes at least one interior cavity or socket 80/86 in the center post 58. The socket 80/86 serves to guide the attachment between the handle 18 and at least one of the 35 instruments 12, 14, and 16. Of course, the number of

- 13 -

sockets 80/86 can vary. The illustrated embodiment shows two sockets 80 and 86. In this arrangement, each instrument 12, 14, and 16 in the system 10 can be fitted to the handle 18.

5 Both first and second sockets 80 and 86 open at the end surface 62 of the center post 58. Both sockets 80 and 86 (see Fig. 6) include interior side walls 76, which extend into the center post 58. Both sockets 80 and 86 include interior end walls 78 10 in the center post 58, spaced below the top wall 50 of the handle 18.

15 Referring to Figs. 9 and 10, the interior side wall 76 of the first socket 80 includes an array of circumferentially spaced grooves 82 with intermediate splines 84. The form and orientation of the grooves 82 and splines 84 are sized to match the form and orientation of the teeth 30 and flutes 32 at the proximal ends 22 of the obturator instrument 12 and the drill bit instrument 16. The first socket 20 80 accepts the tapered flange 28 of either the obturator instrument 12 or the drill bit instrument 16. As Fig. 10 shows, the teeth 30 of the tapered flange 28 mesh in a slip-fit with the grooves 82 of the first socket 80. The running slip-fit allows 25 longitudinal force to be applied to either instrument 12 or 16 through the handle 18. The running slip-fit also prevents relative rotation between either instrument 12 or 16 and the first socket 80, thereby permitting torsional or twisting forces to be applied to either instrument 12 or 16 30 by the handle 18, with an increased mechanical advantage.

35 Because of its larger size, the tapered fitting 40 of the cannula instrument 14 will not fit inside the first socket 80. Instead (see Figs. 11

and 12), the interior side wall 76 of the second socket 86 is sized to accept the tapered fitting 40. The second socket 86 includes an array of circumferentially spaced grooves 88 with intermediate edges 90, which, in form and orientation, match the form and orientation of the teeth 42 and flutes 44 on the tapered fitting 40. The teeth 42 of the tapered fitting 40 mesh in a slip-fit with the grooves 88 of the second socket 86, as Fig. 12 shows. The running slip-fit allows both longitudinal and torsional forces to be applied to the cannula instrument 14 through the handle, with increased mechanical advantage.

Because of its smaller size, the tapered flange 28 of either the obturator instrument 12 or the drill bit instrument 16 will fit inside but not mesh with the second socket 86. The first and second sockets 80 and 86 thereby represent unique attachment sites for different functional instruments.

Referring to Figs. 5 and 6, a first passage 92 extends through the top wall 50 of the handle 18, through the center post 58, and into the first socket 80. The passage 92 is generally aligned with the center of the first socket 80 within the cavity 72. The first passage 92 is sized to pass a conventional surgical guide wire component through the handle 18 and into the lumen 34 of the obturator instrument 12, when fitted in the first socket 80. The interior side wall 76 of the first socket 80 is preferably tapered inward toward the first passage 92, to guide the guide wire through the socket 80 into the first passage 92 without sticking. This arrangement will be described in greater detail later.

- 15 -

Likewise, a second passage 96 extends through the top wall 50 of the handle 18, through the center post 58, and into the second socket 86. The passage 96 is generally aligned with the center of the second socket 86. The second passage 96 is sized to pass either the obturator instrument 12 or the drill bit instrument 16 through the handle 18 and into the lumen 36 of the cannula instrument 14, when fitted in the second socket 86. This arrangement will also be described in greater detail later.

III. The Form and Function of the Running Slip-Fit

The form and function of the running slip-fit between the teeth and flutes 30/32 or 42/44 on the selected instruments 12, 14, and 16 and the grooves and splines 82/84 in the corresponding sockets 80 and 86, allow the physician to fit the selected instrument 12, 14, or 16 to the handle 18 tactiley, without need of visual tracking or confirmation. At the same time, the form and function of the running slip-fit make possible the reliable transmission, with increased mechanical advantage, of both torsional and longitudinal loads by the handle 18 to the selected instrument 12, 14, or 16, without undue slippage or wasted motion. Furthermore, the form and function of the running slip-fit permit quick detachment of the selected instrument 12, 14, or 16 from the handle 18, without sticking or resort to inordinate force.

In the illustrated and preferred embodiment (see Fig. 13), the form and function of the sockets 80 and 86 are realized by use of three grooves 82 circumferentially spaced by intermediate splines 84. Each groove 82 comprises an arcuate section 100 that

extends between two radial sections 102. Each spline 84 is defined between the radial sections 102 of two adjacent grooves 82.

5 The sockets 80 and 86 of the handle 18 can possess different sizes and arcuate relationships, smaller or larger, according to the intended use. For example, posterolateral access to a vertebral body is made using instruments having a larger dimension than instruments used to accomplish a 10 transpedicular access. The sockets 80 and 86 on the handle 18 will therefore be sized differently, depending upon the dimensions of the mating instruments. Practicality and functionality dictate the minimum and maximum dimensions. The size and 15 circumferential spacing of the sockets 80 and 86, as well as the overall dimensions of the handle 18 itself, are selected based upon desired performance, manufacturing, and ease of use criteria.

20 In an exemplary construction to be used with instruments for making a posterolateral access, in the first socket 80, the arcuate sections 100 of the grooves 82 lay at a diameter of about 5.2 mm and the splines 84 lay at a diameter of about 3.3 mm, measured from the center 94 of the first socket 80. In the second socket 86, the arcuate sections 25 100 of the grooves 82 lay along a diameter of about 12.8 mm and the splines 84 lay along a diameter of about 8.1 mm, measured from the center 98 of the second socket 86. In this exemplary embodiment, the 30 first passage 92 has a diameter of about 1.8 mm, and the second passage 96 has a diameter of about 6.5 mm. In this exemplary embodiment, the center post 58 has a major diameter of about 22.8 mm and a minor diameter of about 15.8 mm. The center 94 of the 35 first socket 80 is spaced inward along the main axis

- 17 -

48 from one side of the center post 58 by about 17 mm, while the center 98 of the second socket 86 is spaced inward along the main axis 48 from the same side by about 7.6 mm.

As shown, the arcuate section 100 of each groove 82 extends over an equal arc GA of about 30° , and the grooves 82 are equally spaced apart by an arc SA of about 90° . In this arrangement, the splines 84 are circumferentially spaced apart by an equal arc EA of about 120° .

In addition, in the illustrated embodiment, each spline 84 is rounded or filleted facing into the socket 80/86 to facilitate molding and manufacture. In an exemplary embodiment, the splines

- 18 -

84 in the first socket 80 are filleted at a radius of about 0.3 mm, and the splines 84 in the second socket 86 are filleted at a radius of about 0.6 mm.

5 The form and orientation of the teeth and flutes 30/32 and 42/44 on the mating instrument 12, 16, or 18 are selected to match the form and orientation of the grooves and splines 82/84 of the appropriate socket 80/86. The teeth and flutes 30/32 and 42/44 have as their respective maximum outer diameters a dimension that is about 12% less than the maximum interior diameter of the mating groove 10 and spline 82/84, thereby providing a running slip fit, RC 8.

15 The form and function of the running slip-fit are also influenced by the relative size of the sockets 80/86. Tactile placement is enhanced by maximizing the difference in socket size, so that fitting the wrong instrument in the wrong socket is eliminated. This, in turn, dictates the design of 20 the mating instruments 12, 14, and 16. The difference in socket sizes dictates the difference in sizes of the taper flanges 28 and fittings 40 on the various instruments 12, 14, and 16.

25 The form and function are also affected by the relative orientation of the first and second sockets 80/86 in the center post 58. In the illustrated and preferred embodiment, the first and second sockets 80 and 86 are placed in close side-by-side relationship along the main axis 48 of the 30 handle 18. A groove 82 of the first socket 80 is oriented with a spline 84 of the second socket 86, or vice versa, to minimize the spacing between the two sockets 80 and 86, while maintaining structural integrity.

35 The close, side-by-side orientation of

- 19 -

different size sockets 80 and 86, coupled with the form and orientation of each socket 80 and 86, allows for quick tactile recognition of the proper socket 80/86 on the handle 18 and quick tactile alignment of the mating tapered flanges 28 or tapered fittings 40 on the instrument 12, 14, and 16 in the identified socket 80 or 86. The filleted splines 84 allows for slip-fit engagement against the matching tapered flanges 28 or fittings 40 on the attached instrument 12, 14, or 16. The filleted splines 84 also allow ease of disengagement of the instrument 12, 14, and 16 from the handle 18, without sticking. The form and orientation of the tapered flanges 28 or fittings 40 also allow the application of torsional loads by the handle 18 about the axis of the attached instrument 12, 14, or 16, while the handle 18 applies a longitudinal load along the axis of the attached instrument 12, 14, or 16.

20

IV. Kit for Packaging the System

25

30

As shown in Fig. 14, a kit 104 is provided for storing the one or more functional instruments 12, 14, and 16 in association with the handle 18 prior to use. The kit 104 also includes other components 106 and 108, which are intended to be used in association with the instruments 12, 14, and 16 and handle 18. For example, the kit 104 shown in Fig. 14 includes a guide pin component 106 and a catheter component 108, which carries a diagnostic or therapeutic element 110 for deployment in the targeted interior body region. Though not shown in Fig. 14, the kit 104 can also include a conventional spinal needle assembly 152, which will be described in greater detail later.

35

The kit 104 can take various forms. In the

- 20 -

illustrated embodiment, the kit 104 comprises a sterile, wrapped assembly.

In this assembly (see Fig. 15 also), the kit 104 includes an interior tray 112 made, e.g., 5 from die cut cardboard, plastic sheet, or thermo-formed plastic material. The tray 112 includes spaced apart tabs 114, which hold the handle 18, instruments 12, 14, and 16, and components 106 and 108 in a secure position during sterilization and 10 storage prior to use.

Preferably, the tray 112 presents the handle 18, instruments 12, 14, and 16, and components 106 and 108 in an ordered, organized 15 layout, which is arranged to aid the physician in carrying out the intended procedure. For example, the layout of the tray 112 can present the instruments 12, 14, and 16 and components 106 and 108 in top-to-bottom order, according to sequence of intended use. For example, in a typical bone access 20 procedure (as will be demonstrated in greater detail later), the guide pin component 106 is deployed first, followed by the obturator instrument 12, then the cannula instrument 14, then the drill bit instrument 16, and lastly the catheter component 25 108. Accordingly, the tray 112 packages these instruments and components in a top-to-bottom order, with the guide pin component 106 topmost, the obturator instrument 12 next, the cannula instrument 14 next, the drill bit instrument 16 next, and the catheter component lowermost 108. When a spinal 30 needle assembly 152 is included in the kit 104, the spinal needle assembly 152 is mounted above the guide pin component 106.

In this layout, the handle 18 is packaged 35 to the side of the instruments 12, 14, and 16. The

- 21 -

tray 112 can include written labels 116 identifying the handle 18 and each instrument and component contained in the kit 104.

When packaged as a sterile assembly, the 5 kit 104 includes an inner wrap 118, which is peripherally sealed by heat or the like, to enclose the tray 112 from contact with the outside environment. One end of the inner wrap includes a conventional peal-away seal 120, to provide quick 10 access to the tray 112 at the instant of use, which preferably occurs in a sterile environment, such as within an operating room.

When packaged as a sterile assembly, the 15 kit 104 also includes an outer wrap 122, which is also peripherally sealed by heat or the like, to enclosed the inner wrap. One end of the outer wrap 122 includes a conventional peal-away seal 124, to provide access to the inner wrap 118 and its contents. The outer wrap 122 can be removed from 20 the inner wrap 118 in anticipation of imminent use, without compromising sterility of the handle 18, instruments 12, 14, and 16, and components 106 and 108 themselves.

Each inner and outer wrap 118 and 122 25 includes a peripherally sealed top sheet 126 and bottom sheet 128 (see Fig. 15). In the illustrated embodiment, the top sheet 126 is made of transparent plastic film, like polyethylene or MYLAR™ material, to allow visual identification of the contents of 30 the kit 104. The bottom sheet 128 is made from a material that is permeable to ETO sterilization gas, e.g., TYVEK™ plastic material (available from DuPont).

The kit 104 also preferably includes in the 35 tray 112 directions 130 for using the handle 18, the

- 22 -

instruments 12, 14, and 16, and the components 106 and 108 to carry out a desired procedure. An exemplary procedure which the directions can describe will be explained later.

5 When packaged as a sterile assembly, the directions 130 can include the statement "For Single Patient Use Only" (or comparable language) to affirmatively caution against reuse of the contents of the kit 104. The directions 130 also preferably 10 affirmatively instruct against resterilization of the handle 18, instruments 12, 14, and 16, or components 106 and 108 and also instructs the physician or user to dispose of the entire contents 15 of the kit 104 upon use in accordance with applicable biological waste procedures.

20 The presence of the handle 18, instruments 12, 14, and 16, and components 106 and 108 packaged in the sterile kit 104 verifies to the physician or user that the contents are sterile and have not been subjected to prior use. The physician or user is thereby assured that the handle 18, instruments 12, 14, and 16, and components 106 and 108 meet 25 established performance and sterility specifications.

30 It should be appreciated that the instruments and components contained in the kit 104 can be packaged into several, smaller functional kits. For example, a tool kit can package a spinal needle assembly, a guide pin component, an obturator instrument, a cannula instrument, and a drill bit instrument, together with the handle. A separate catheter kit can package the catheter component. Another separate cement kit can package a cement nozzle and tamp. Figs. 14 and 15 illustrate one of 35 many different possible embodiments.

- 23 -

v. Illustrativ Use of the System

The following describes use of the handle 18, instruments 12, 14, and 16, and components 106 and 108 shown in Fig. 14 packaged in the kit 104 in the context of treating bones. This is because these items can be advantageously used for this purpose. Still, it should be appreciated that the handle 18 is not limited to use in the treatment of bones. The handle 18 can be used in association with virtually any hand-held instrument intended to contact tissue to perform a diagnostic or therapeutic function.

The handle 18, instruments 12, 14, and 16, and components 106 and 108 will described with regard to the treatment of human vertebra. It should be appreciated, however, their use is not limited to human vertebrae. The handle 18 can be used in association with hand-held instruments in the treatment of diverse human or animal bone types.

A typical vertebra 130 (see Figs. 16 and 17) includes a vertebral body 132, which extends on the anterior (i.e., front or chest) side of the vertebra 130. The vertebral body 132 has the shape of an oval disk. The vertebral body 132 includes an exterior formed from compact cortical bone 136. The cortical bone 136 encloses an interior volume 138 of reticulated cancellous, or spongy, bone 140 (also called medullary bone or trabecular bone).

The spinal cord 142 passes through the spinal canal of the vertebra 132. The vertebral arch 144 surrounds the spinal canal 142. The pedicles 146 of the vertebral arch adjoin the vertebral body 134. The spinous process 148 extends from the posterior of the vertebral arch 144, as do the left and right transverse processes 150.

Referring first to Fig. 18, in a typical procedure, a patient lies on an operating table, while the physician introduces a conventional spinal needle assembly 152 into soft tissue (designated S in the drawings) in the patient's back. The patient can lie facedown on the table, or on either side, or at an oblique angle, depending upon the physician's preference. Indeed, the procedure can be performed through an open anterior procedure or an endoscopic anterior procedure.

The spinal needle assembly 152 comprises a stylet 154 slidably housed within a stylus 156. The assembly 152 typically has, for example, about an 18 gauge diameter. Other gauge diameters can and will be used to accommodate appropriate guide pins.

Under radiologic or CT monitoring, the physician advances the assembly 152 through soft tissue S down to and into the targeted vertebra 132, as Fig. 18 shows. The physician will typically administer a local anesthetic, for example, lidocaine, through assembly 152. In some cases, the physician may prefer other forms of anesthesia.

The physician directs the spinal needle assembly 152 to penetrate the cortical bone 136 and the cancellous bone 140 of the targeted vertebra 132. Preferably the depth of penetration is about 60% to 95% of the vertebral body 134.

Fig. 18 shows gaining access to cancellous bone 140 through the pedicle 146, which is called transpedicular access. However, posterolateral access, through the side of the vertebral body 134 may be indicated, based upon the objectives of the treatment or for other reasons based upon the preference of the physician.

Referring now to Fig. 19, after positioning

- 25 -

the spinal needle assembly 152 in cancellous bone, the physician holds the stylus 156 and withdraws the stylet 154. It is at this time, or slightly before, that the outer and inner wraps 118 and 122 of the 5 kit 104 can be removed, exposing the components carried on the tray 112 for use.

10 The physician first acquires the guide pin component 106 from the tray 112. As Fig. 20 shows, while still holding the stylus 156, the physician slides the guide pin component 106 through the stylus 156 and into the cancellous bone 140. As Fig. 21 shows, the physician now removes the stylus 156, leaving the guide pin component 106 deployed within the cancellous bone 140.

15 The physician next acquires the obturator instrument 12 and the handle 18 from the tray 112. As Fig. 22 shows, the physician slides the obturator instrument 12 over the guide pin component 106, distal end first. The physician slides the guide pin 20 component 106 through the first passage 92 and the first socket 80 of the handle 18. As previously described, the interior side wall 76 of the first socket 80 is preferably tapered inward to guide the guide wire into the first passage 92 without sticking. The physician slides the handle 18 along the guide pin component 106 toward the tapered flange 28 of the obturator instrument 12, until 25 achieving a running slip-fit between the first socket 80 and the tapered flange 28, in the manner previously described. The obturator instrument 12 30 is now ready for use.

35 As Fig. 22 shows, the physician makes a small incision (designated I in Fig. 22) in the patient's back. The physician twists the handle 18 while applying longitudinal force to the handle 18.

- 26 -

In response, the tapered surface 26 of the obturator instrument 12 rotates and penetrates soft tissue through the incision I. The physician may also gently tap the handle 18, or otherwise apply appropriate additional longitudinal force to the handle 18, to advance the obturator instrument 12 through the soft tissue S along the guide pin component 106 down to the entry pedicle 146. The physician can also tap the handle 18 with an appropriate striking tool to advance the sharpened surface 26 of the obturator instrument 12 into the pedicle 146 to secure its position, as Fig. 23 shows.

The physician next slides the handle 18 along the guide pin component 106 away from the obturator instrument 12 to disengage the tapered flange 28 from the first socket 80. The physician then proceeds to slide the handle 18 completely off the guide pin component 106. The physician acquires the cannula instrument 14 from the tray 112.

As Fig. 24 shows, the physician slides the cannula instrument 14 over the guide pin component 106, distal end first, and, further, over the obturator instrument 12, until contact between the end surface 38 and tissue occurs. The physician now slides the guide pin component 106 through the second passage 96 and second socket 86 of the handle 18. The physician slides the handle 18 toward the tapered fitting 40 of the cannula instrument 14 until a running slip-fit occurs between the second socket 86 and the tapered fitting 40, as previously described. The cannula instrument 14 is now ready for use.

As Fig. F shows, the physician applies appropriate twisting and longitudinal forces to the

- 27 -

handle 18, to rotate and advance the cannula instrument 14 through soft tissue along the obturator instrument 12. As Fig. 25 shows, when the end surface 38 of the cannula instrument 14 contacts cortical bone 136, the physician appropriately taps the handle with a striking tool to advance the end surface 38 into the pedicle 146 to secure its position.

As Fig. 26 shows, the physician now withdraws the obturator instrument 12, sliding it off the guide pin component 106, to leave the guide pin component 106 and the cannula instrument 14 in place, as Fig. 27 shows. The physician slides the handle 18 along the guide pin component 106 away from the cannula instrument 14 to disengage the tapered fitting 40 from the second socket 86. The physician then slides the handle 18 completely off the guide pin component 106. The physician now acquires the drill bit instrument 16 from the tray 112.

The physician slides the drill bit instrument 16 over the guide pin component 106, distal end first, through the cannula instrument 14 until contact with the bone tissue occurs. The physician next leads the guide pin component 106 through the first passage 92 and first socket 80 of the handle 18. As previously described, the preferred taper of the first socket 80 guides the guide wire through the socket 80 into the first passage 92 without sticking. As Fig. 28 shows, the physician slides the handle 18 along the guide pin component 106 toward the tapered flange 28 of the drill bit instrument 16, until a running slip-fit occurs between the first socket 80 and the tapered flange 28, as previously described. The drill bit

instrument 16 is now ready for use.

As Fig. 29 shows, under X-ray control (or using another external visualizing system), the physician applies appropriate twisting and longitudinal forces to the handle 18, to rotate and advance the cutting edge 46 of the drill bit instrument 16 to open a passage 158 through the bone tissue and completely into the cancellous bone 140. The drilled passage 158 preferable extends no more than 95% across the vertebral body 134.

The physician now slides the handle 18 along the guide pin component 106 away from the drill bit instrument 16 to disengage the tapered flange 28 from the first socket 80. The physician, further, slides the handle 18 completely off the guide pin component 106.

The physician can now remove the drill bit instrument 16 and the guide pin component 106, leaving only the cannula instrument 14 in place, as Figs. 30 and 31 show. The passage 158 made by the drill bit instrument 16 remains. Access to the cancellous bone 140 has been accomplished.

The physician can now acquire the catheter component 108 from the tray 112. The physician can advance a diagnostic or therapeutic element 110 carried by the catheter component 108 through the cannula instrument 14 and passage 158 into the interior volume 138 of the vertebral body 134.

The diagnostic or therapeutic element 110 of the catheter component 108 can be configured to perform various functions. For example, the distal element 110 can comprise a biopsy instrument, to obtain samples of cancellous bone. Alternatively, the distal element 110 can be a stylet to introduce a medication or the like into cancellous bone. Still

- 29 -

alternatively (as shown in the illustrated embodiment), the distal element 110 can comprise an expandable body to compact cancellous bone 140 and form a cavity in the vertebral body 134, in the manner disclosed in United States Patent Numbers 5 4,969,888 and 5,108,404, which are incorporated herein by reference. Upon compaction of cancellous bone, the distal element 110 can also include a nozzle to inject a flowable bone cement material 10 into the formed cavity.

VI. Alternative Handle Configurations

As before explained, the shape of the handle 18 can vary. Figs. 5 to 8 show a handle 18 with a generally T-shaped configuration.

A. Round Handle

Figs. 32 to 34 show a representative alternative embodiment, in which a handle 218 has a general round configuration, made from a molded rigid plastic or metal material. The round handle 218 is also shaped to be comfortably and securely 15 20 grasped by a normal human hand. In a representative embodiment, the handle 218 measures about 38 mm in diameter.

The handle 218 includes a top wall 160 and 25 a peripheral side wall 162. The junction of the side wall 162 with the top wall 160 is preferably rounded to provide a comfortable grip. In addition, the side wall 162 includes a series of circumferentially spaced scallops 164 to assist the transmission of 30 turning forces. In the illustrated embodiment, seven equally spaced scallops 164 are present to provide an appropriate turning resolution. The scallops 164 are each curved inwardly to comfortable accommodate 35 the dimension of a thumb (e.g., with a radius of curvature of about 9mm to 10 mm). The top wall 160

- 30 -

and the side wall 162 can be roughened or otherwise textured to enhance the over grip.

In the illustrated embodiment, the top wall 160 includes circumferentially spaced voids 166 aligned with each scallop 164. The voids 166 reduce the overall weight of the handle 218 and are arranged to provide optimal balance for the handle 218.

Like the T-shaped handle 18, the round handle 218 includes a center post 168, which is integrally molded to the walls 160 and 162 about the geometric center 170 of the handle 218. The center post 168 extends downward from the top wall 160 along the geometric center 170 between the side wall 162. The center post has an exposed end surface 172, which terminates below the lower edge 176 of the side wall 162. In an exemplary embodiment, the center post 168 has an outside diameter of about 22.8 mm, which is about the same outside diameter as the center post 58 of the T-shaped handle 18.

The round handle 218 likewise includes the first and second sockets 80 and 86 to enable attachment of the various instruments, in the same manner as previously described. The sockets 80 and 86 include arrays of grooves 82 circumferentially spaced by splines 84. The form, orientation, and size of the grooves 82 and splines 84 can be same as already described and shown in Fig. 13 to match the form and orientation of the teeth and flutes 30/32 and 42/44 at the proximal ends of the obturator instrument 12 and the drill bit instrument 14 (in the first socket 80) and the cannula instrument 12 (in the second socket 86). The tapered flanges 28 and fitting 40 thereby mesh in a running slip-fit in the appropriate first and second sockets 80 and 86.

- 31 -

As explained with respect to the T-shaped handle 18, the comparable running slip-fit that the round handle 218 provides, allows both longitudinal and twisting forces to be applied to the attached instrument 12, 14, and 16 through the handle 218. The different sizes of the first and second sockets 80 and 86 on the round handle 218 likewise represent the same sort of unique attachment sites for the different functional instruments, as previously explained for the T-shaped handle 18.

Like the T-shaped handle 18, first and second passages 92 and 96 extend through the top wall 160 of the round handle 218 and into the first and second sockets 80 and 86, respectively. The first passage 92 is sized to pass a conventional surgical guide wire through the handle 218 and into the lumen of the obturator instrument 12 or drill bit instrument 165 fitted in the first socket 80. The second passage 96 is sized to pass either the obturator instrument 12 or the drill bit instrument 16 through the handle 218 and through the lumen 36 of the cannula instrument 14 fitted in the second socket 86.

B. Anvil Handle

Figs. 35 to 38 show another alternative embodiment of a handle 318, which embodies features of the invention. In this embodiment, the handle 318 is characterized by an elliptical "anvil" shape.

The elliptical handle 318 has a top wall 176 and a side wall 178 made from a molded rigid plastic or metal material. The handle 318 is dimensioned to be grasped between the forefinger and the thumb, with the top wall 176 facing upward, as Fig. 35 shows. The shape and orientation, when held by the physician, are intended to facilitate the

- 32 -

application of greater tapping or striking forces, to advance an attached instrument 12/14/16 through denser or harder tissue, such as skeleton bone.

5 In an exemplary embodiment, the top wall 176 has a length dimension along its major axis 180 of about 57.2 mm and a length dimension along its minor axis 182 of about 50.8 mm. In the exemplary embodiment, the side wall 178 extends below the top wall 176 for a distance of about 11.3 mm.

10 The side wall 178 is chamfered inward, to present concave front and rear gripping surfaces 184 and 186, which are spaced apart along the major axis 180. In the illustrated embodiment, the radius of chamfer for the front surface 184 is intended to match the joint radius of the forefinger. The radius of the chamfer for the rear surface 186 is intended to match the joint radius of the thumb. Preferably, both the forward and rearward surfaces 184 and 186 are knurled or roughed to enhance the 15 physician's grip.

20 As Fig. 35 shows, the inward chamfer of the side wall 178 shelters the physician's hand from the top wall 176, on which the striking forces are applied. The top wall 176 is also preferably bowed upward, to present a raised striking surface, which further distances the physician's hand from the 25 point of impact of the striking instrument.

25 A portion of the rear gripping surface 186 is cut away to form two interior sockets 188 and 190. The sockets 188 and 190 are axially oriented. The second socket 190 possesses an interior dimension, which is larger than the interior dimension of the first socket 188.

30 The form and size of the first interior dimension of the first socket 188 is intended to

- 33 -

receive the proximal end 22 of either the obturator instrument 12 or the drill bit instrument 16, but not the cannula instrument 14, in a releasable interference snap-fit. In this arrangement, the proximal end of the instrument 12 and 16 can include a tapered flange 28, as already described, but need not. The releasable snap-fit stabilizes the instrument 12 or 16 in the first socket 188 for the application of a striking force on the top wall 176.

In like fashion, the form and size of the second interior dimension of the second socket 190 is intended to receive the proximal end 22 of the cannula instrument 14, but not the obturator instrument 12 or the drill bit instrument 16, in a releasable interference snap-fit. In this arrangement, the proximal end 22 of the cannula instrument 14 can include a tapered fitting 40, as already described, but need not. The releasable snap-fit stabilizes the cannula instrument 14 in the second socket 190 for the application of a striking force on the top wall 176.

Since the first and second sockets 188 and 190 extend through the handle 318, the handle 318 will accommodate the passage of a guide pin component 106 and the like through any instrument attached to the handle 318. For the same reason, the handle 318 will also accommodate the passage of smaller diameter instrument within a larger diameter instrument held by the handle 318.

The form and orientation of the sockets 188 and 190 in the elliptical handle 318 also permit the physician, using only tactile sensing, to insert the selected instrument into the desired socket 188 or 190 and remove the attached instrument from the socket 188 or 190, without need of visual

intervention.

It should be appreciated that the sockets 80 and 86 shown in the T-shaped handle 18 in a side-by-side arrangement (see Figs. 5 to 8), can, in an alternative embodiment, be stacked one above the other in the manner shown for the anvil handle 318 in Fig. 36. In this arrangement, the smaller first socket 80 is stacked concentrically above the larger second socket 86. The passage 92 extends along the center axis of the sockets 80 and 86, opening into the first socket 80 and thereby serving both sockets 80 and 86. This alternative construction allows central placement of all the instruments carried by the handle.

All preceding embodiments show the handle as possessing female attachment components (i.e., the sockets) to receive male handle attachment sites (i.e., the fittings) on the instruments. Of course, this arrangement can be reversed and still provide all the benefits of the invention. That is, as shown in Fig. 39, a handle 400 can carry male handle attachment sites 402 and 404 that mate in the desired running slip fit fashion with female attachment components 406, 408, and 410 carried by the instruments 412, 414, and 416, respectively. In Fig. 39, attachment site 402 uniquely mates with the attachment components 406 and 410, while attachment site 404 uniquely mates with attachment component 408. Alternatively, the handle 400 can carry one male attachment site and one female attachment component, and one instrument can likewise carry a male attachment site, while another instrument can carry a female attachment component. It should be fully appreciated that many attachment site/component combinations on the instruments and

- 35 -

handle are possible. Regardless of the particular combination selected, the use of the handle 400 in association with the instruments 412, 414, and 416 is identical to that previously described in the context of other embodiments.

The foregoing description demonstrates the applicability of a handle made according to the invention for use in association with a wide assortment of different instruments or tools, and for use both inside and outside the medical field. The handle provides error-free coupling to different instruments or tools, and, further, uniquely allows coupling to one instrument or tool which has nested within it another instrument or tool. The shape and size of the handle can also vary significantly, limited only by the practicalities surrounding hand-held use and manipulation.

The features of the invention are set forth in the following claims.

We Claim:

1. A surgical system comprising
a first functional instrument including a
first handle attachment site characterized by a
first geometry,
5 a second functional instrument including a
second handle attachment site characterized by a
second geometry different than the first geometry,
and
10 a handle for manipulating the first and
second functional instruments when in use, the
handle including a first component configured to
removably engage the first handle attachment site
but not the second handle attachment site, and a
second component configured to removably engage the
15 second handle attachment site but not the first
handle attachment site.
2. A system according to claim 1
wherein the handle is adapted, in use, to
transmit longitudinal force to the instrument
removably engaged by the handle.
3. A system according to claim 1
wherein the handle is adapted, in use, to
transmit rotational force to the instrument
removably engaged by the handle.
4. A system according to claim 1
wherein the handle is adapted, in use, to
transmit both longitudinal and rotational forces to
the instrument removably engaged by the handle.
5. A system according to claim 1
wherein the handle is adapted, in use, to
receive a striking force.
6. A system according to claim 1
wherein the second geometry differs from
the first geometry at least in size.

- 37 -

7. A system according to claim 1
wherein at least one of the first and
second handle attachment sites comprises a fitting,
and

5 wherein at least one of the first and
second components comprises a socket configured to
engage the fitting.

8. A system according to claim 7
wherein the fitting is tapered.

9. A system according to claim 7 or 8
wherein the socket engages the fitting in
a releasable slip-fit.

10. A system according to claim 7
wherein the socket is tapered.

11. A system according to claim 1
wherein at least one of the first and
second handle attachment sites comprises a socket,
and

5 wherein at least one of the first and
second components comprises a fitting configured to
engage the socket.

12. A system according to claim 11
wherein the fitting is tapered.

13. A system according to claim 11
wherein the fitting engages the socket in
a releasable slip-fit.

14. A system according to claim 11
wherein the socket is tapered.

15. A system according to claim 1
wherein the first component is adjacent to
the second component on the handle.

16. A system according to claim 1
wherein the handle includes a passageway
extending into at least one of the first and second
components and accommodating a guide pin component

5 for the respective first and second instrument while the respective instrument is removably engaged by the handle.

17. A system according to claim 1 wherein the handle includes a passageway extending into at least one of the first and second components and accommodating passage of one of the 5 first or second instruments through the other one of the instruments while the other one of the instruments is removably engaged by the handle.

18. A system according to claim 1 wherein the handle is generally T-shaped.

19. A system according to claim 1 wherein the handle is generally round.

20. A system according to claim 1 wherein the handle is generally elliptical 5 in shape.

21. A surgical system comprising a first functional instrument including a handle attachment site and an interior bore, a second instrument sized for passage 5 through the interior bore, and a handle for manipulating the first functional instrument when in use, the handle including a component configured to removably engage the handle attachment site, and a passageway extending into the component for passing the second instrument through the handle and interior bore 10 while the first functional instrument is removably engaged by handle.

22. A system according to claim 21 wherein the second functional instrument comprises a guide pin for the first functional instrument.

23. A system according to claim 21

- 39 -

wherein the first functional instrument comprises a cannula for the second functional element.

24. A system according to claim 21
wherein the second instrument includes a
second handle attachment site, and

wherein the handle includes a second component configured to removably engage the second handle attachment site.

25. A system according to claim 21 wherein the handle is adapted, in use, to transmit longitudinal force to the first functional instrument removably engaged by the handle.

26. A system according to claim 21 wherein the handle is adapted, in use, to transmit rotational force to the first functional instrument removably engaged by the handle.

27. A system according to claim 21 wherein the handle is adapted, in use, to transmit both longitudinal and rotational forces to the first functional instrument removably engaged by the handle.

28. A surgical system for accessing bone comprising

a functional instrument including a first handle attachment site characterized by a first geometry,

a cannula instrument including a second handle attachment site characterized by a second geometry different than the first geometry, and

a handle for manipulating the functional instrument and the cannula instrument when in use, the handle including a first component configured to removably engage the first handle attachment site but not the second handle attachment site, and a

- 40 -

15 second component configured to removably engage the second handle attachment site but not the first handle attachment site.

29. A system according to claim 28 wherein the handle is adapted, in use, to transmit longitudinal force to the functional instrument or the cannula instrument removable engaged by the handle.

5 30. A system according to claim 28 wherein the handle is adapted, in use, to transmit rotational force to the functional instrument or the cannula instrument removable engaged by the handle.

31. A system according to claim 28 wherein the handle is adapted, in use, to transmit both longitudinal and rotational forces to the functional instrument or the cannula instrument removable engaged by the handle.

32. A system according to claim 28 wherein the cannula instrument includes an interior bore,

5 wherein the functional instrument is sized for passage through the interior bore, and wherein the handle includes a passageway extending into the second component for passing the functional instrument through the handle and interior bore of the cannula instrument while the cannula instrument is removably engaged by the handle.

10 33. A system according to claim 28 wherein the functional instrument includes an interior bore sized to receive a guide wire, and wherein the handle includes a passageway 5 extending into the first component for passing a guide wire through the handle and interior bore of

- 41 -

the functional instrument while the functional instrument is removably engaged by the handle.

34. A system according to claim 28 wherein the functional instrument comprises an obturator.

35. A system according to claim 28 wherein the functional instrument comprises a drill bit.

36. A surgical system for accessing bone comprising

a drill bit instrument for penetrating bone in response to rotation, the drill bit instrument including a handle attachment site, and

5 a handle configured to be hand-held by a user and including a component configured for releasable engagement with the handle attachment site to impart rotation to the drill bit instrument in response to rotation of the handle while hand-held by the user.

37. A system according to claim 36 and further including a cannula instrument having an interior bore to accommodate passage of the drill bit instrument, the cannula instrument including a second handle attachment site, and

5 wherein the handle includes a second component configured for releasable engagement with the second handle attachment site.

38. A system according to claim 36 wherein the handle includes a passageway extending into the second component for passing the drill bit instrument through the handle and 5 interior bore of the cannula instrument while the cannula instrument is removably engaged by the handle.

39. A method for removing bone comprising

- 42 -

the steps of

5 placing an instrument having a distal drill bit end in contact with bone, the distal drill bit end being operative for penetrating bone in response to application of rotational force,

engaging an proximal end of the instrument to a releasable handle configured to be hand-held by a user, and

10 rotating the handle while hand-held by the user to manually impart rotation to the distal drill end, thereby removing bone.

40. A surgical kit comprising

a functional instrument,

5 a handle including a socket to releasably engage the functional instrument for manipulating the functional instruments when in use,

an overwrap defining a sealed enclosure holding the functional instrument and handle until use.

41. A kit according to claim 40

and further including a component intended to be used in association with the functional instrument, and

5 wherein the overwrap holds the functional instrument, the handle, and the component until use.

42. A kit according to claim 41

wherein the component comprises a guide pin.

43. A kit according to claim 41

wherein the component comprises a catheter carrying a diagnostic or therapeutic element.

44. A kit according to claim 40

and further including a tray enclosed in the overwrap holding the functional instrument and the handle prior to use.

- 43 -

45. A kit according to claim 40
and further including directions for using
the functional instrument enclosed in the overwrap.

46. A kit according to claim 40
and further including a second functional
instrument different than the first functional
instrument,

5 wherein the handle includes an attachment
component to releasably engage the second functional
instrument for manipulating the second functional
instruments when in use, and

10 wherein the overwrap defines a sealed
enclosure holding the first functional instrument,
the second functional instrument, and the handle
until use.

5 47. A kit according to claim 46
and further including a tray enclosed in
the overwrap holding the first functional
instrument, the second functional instrument, and
the handle prior to use.

48. A kit according to claim 47
wherein the tray holds the first functional
instrument and second functional instrument in a
prearranged layout to facilitate use.

5 49. A kit according to claim 46
and further including a component intended
to be use in association with at least one of the
first and second functional instruments, and

wherein the overwrap holds the first
functional instrument, the second functional
instrument, the component, and the handle until use.

50. A kit according to claim 49
wherein the component comprises a guide
pin.

51. A kit according to claim 49

- 44 -

wherein the component comprises a catheter carrying a diagnostic or therapeutic element.

52. A kit according to claim 40 or 46 wherein the overwrap defines a sealed sterile enclosure.

53. A kit according to claim 52 wherein the overwrap includes a material permeable to ETO sterilization gas.

54. A surgical kit for accessing bone comprising

an obturator instrument,

a cannula instrument,

5 a drill bit instrument,

a handle including attachment components to releasably engage the obturator instrument, the cannula instrument, and the drill bit instrument for use, and

10 an overwrap defining a sealed enclosure holding the obturator instrument, the cannula instrument, the drill bit instrument, and handle until use.

55. A kit according to claim 54

and further including a component intended to be use in association with at least one of the obturator, cannula, and drill bit instruments, and

5 wherein the overwrap holds the obturator, cannula, and drill bit instruments, the handle, and the component until use.

56. A kit according to claim 54 and further including a tray enclosed in the overwrap holding the obturator, cannula, and drill bit instruments and the handle prior to use.

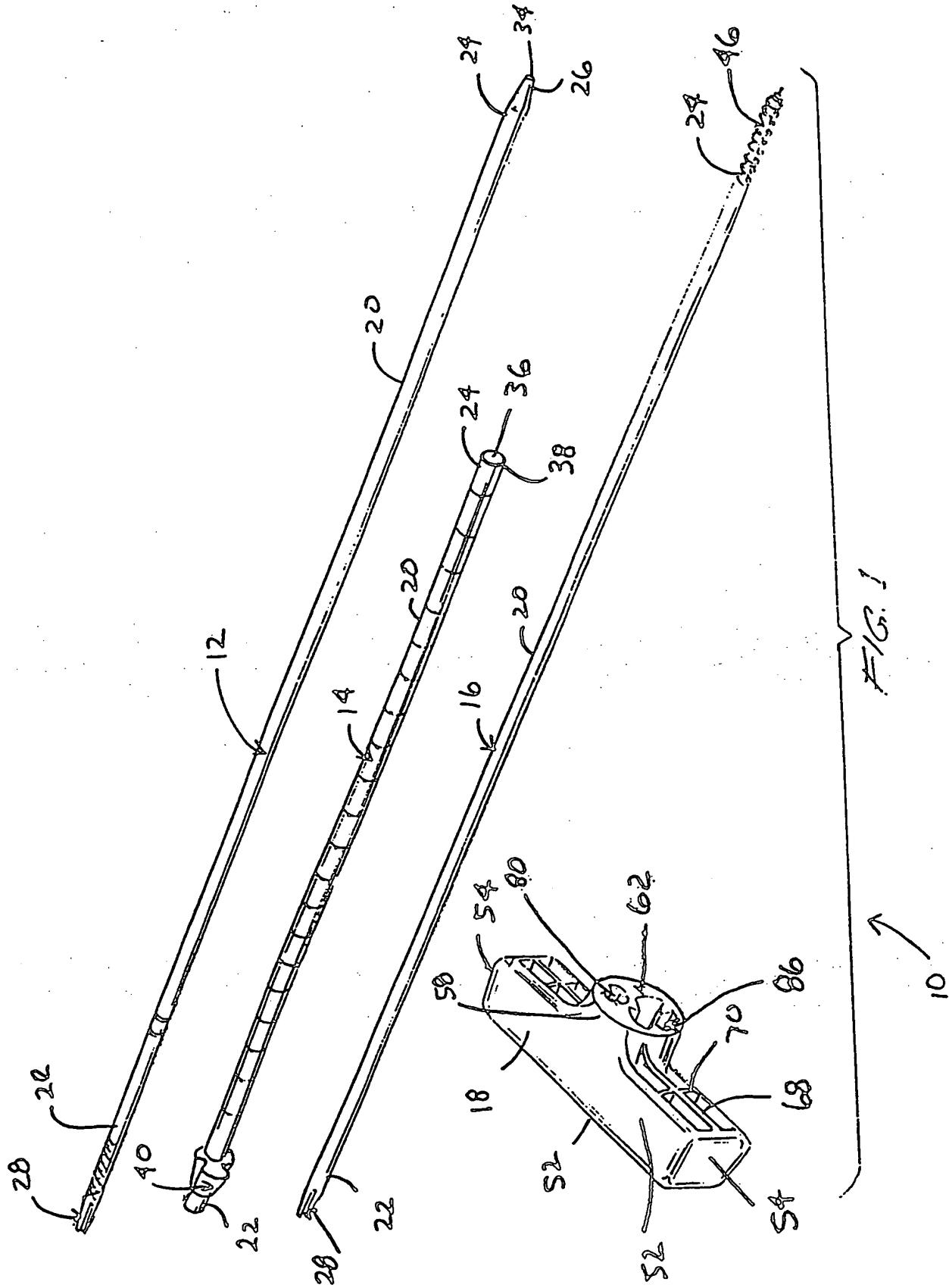
57. A kit according to claim 56 wherein the tray holds the obturator, cannula, and drill bit instruments in a prearranged

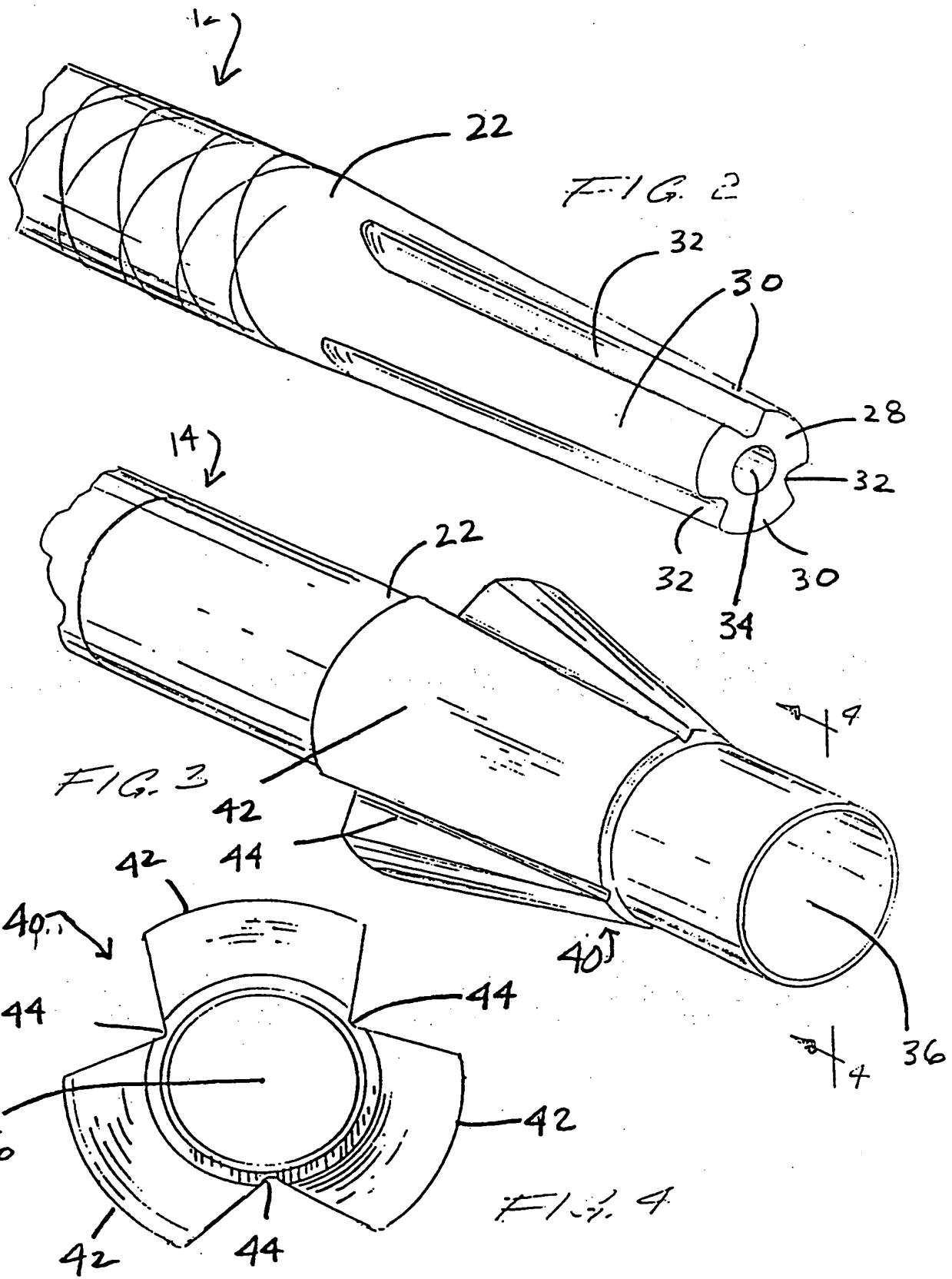
- 45 -

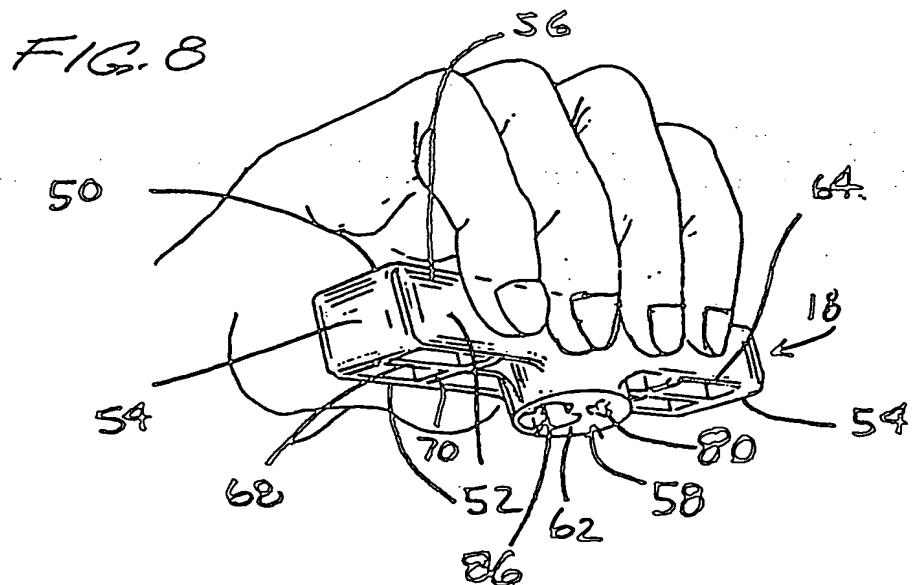
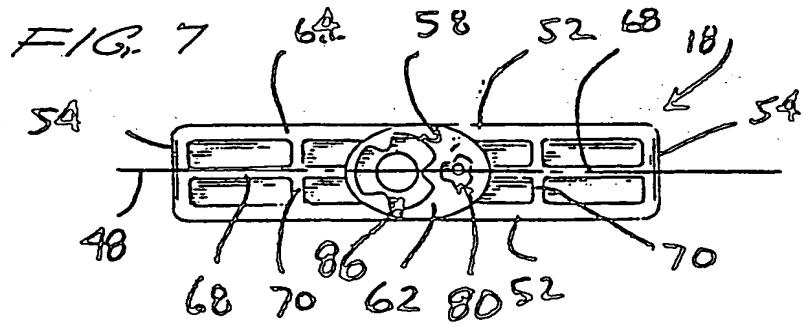
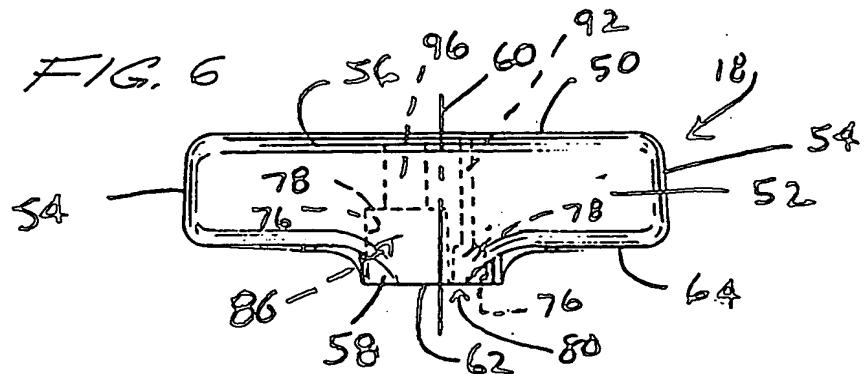
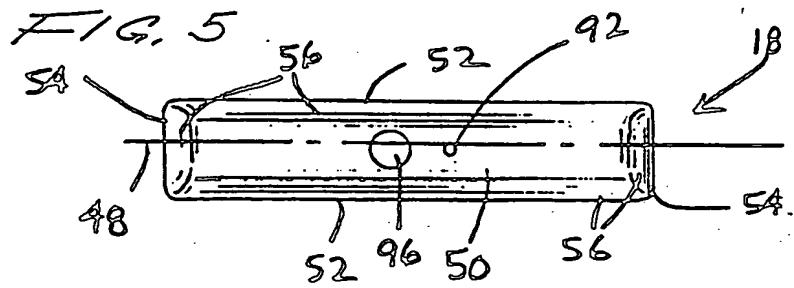
layout to facilitate use.

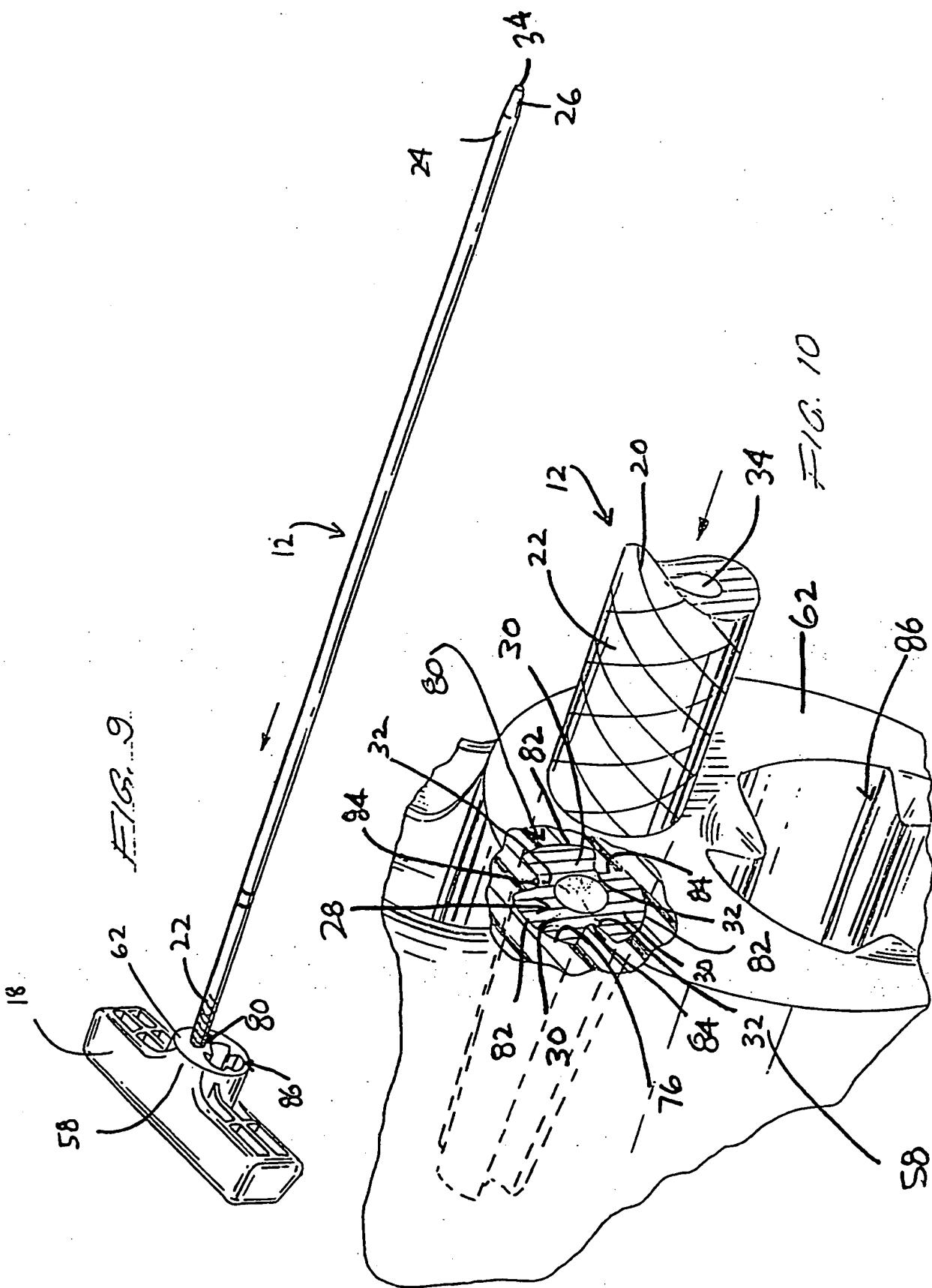
58. A kit according to claim 54
wherein the overwrap defines a sealed
sterile enclosure.

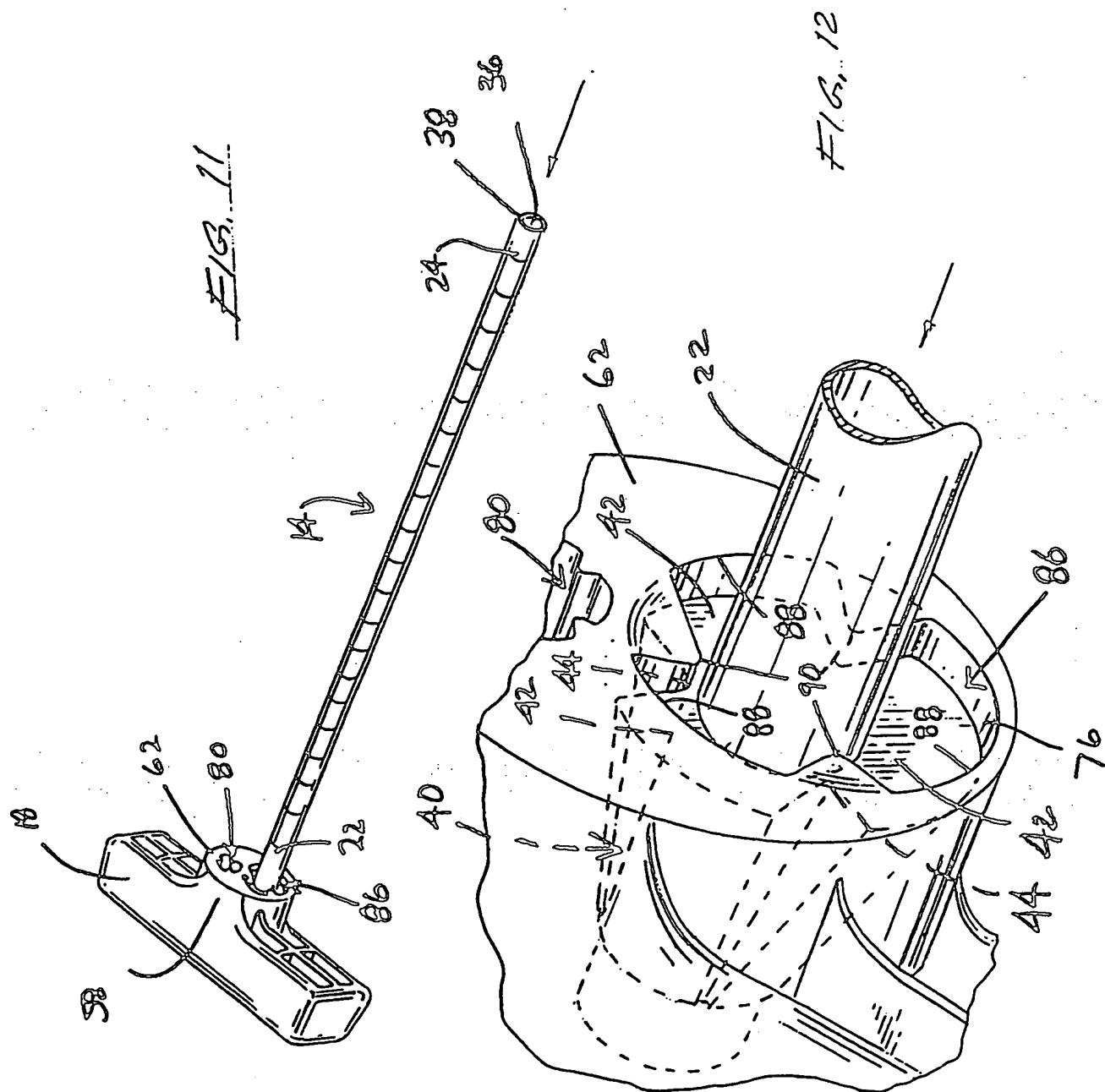
59. A kit according to claim 58
wherein the overwrap includes a material
permeable to ETO sterilization gas.











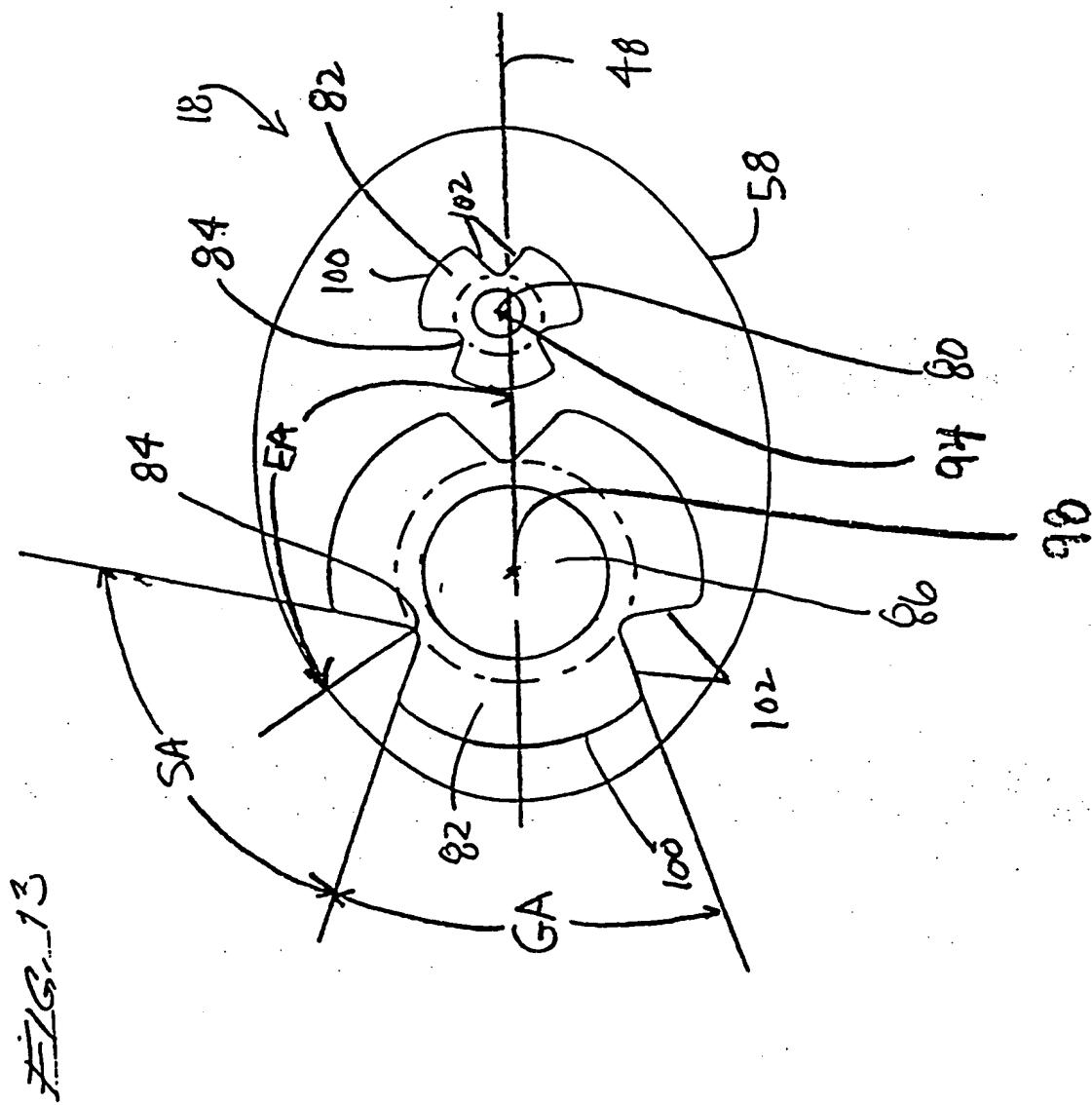


FIG. 14

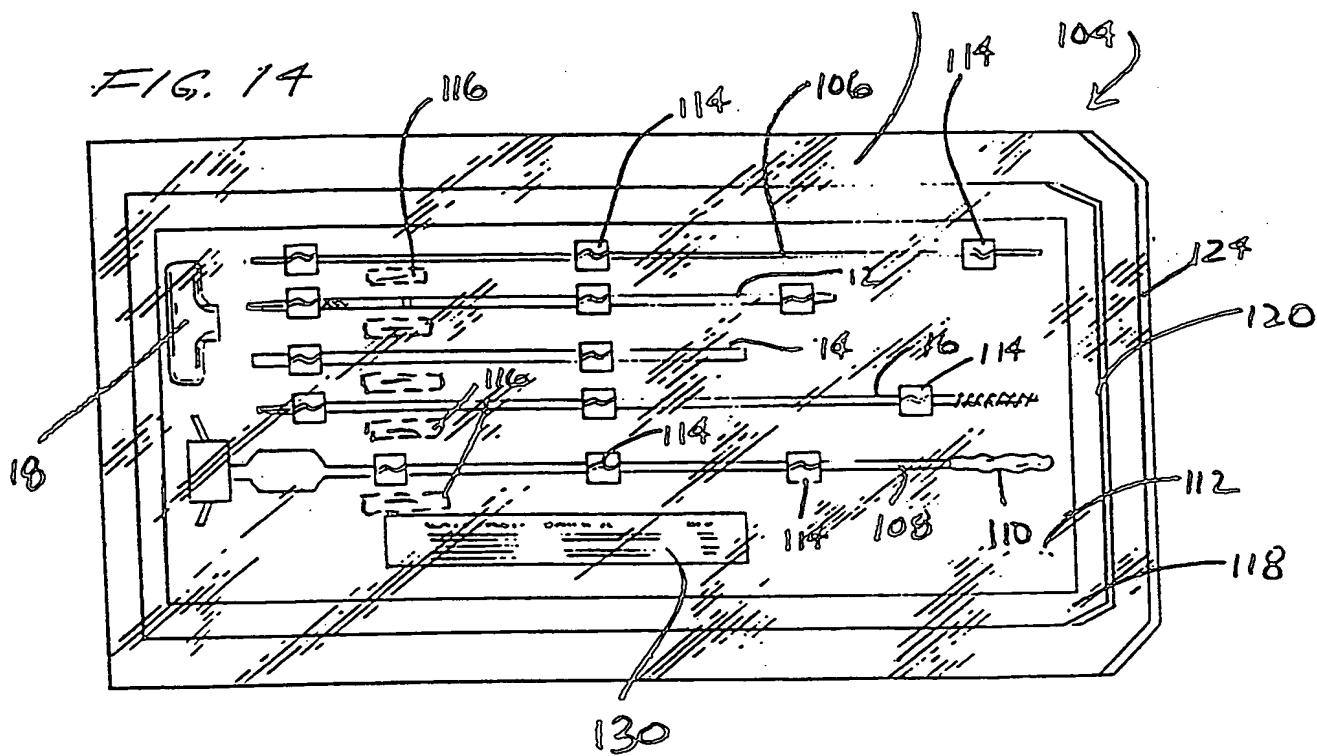
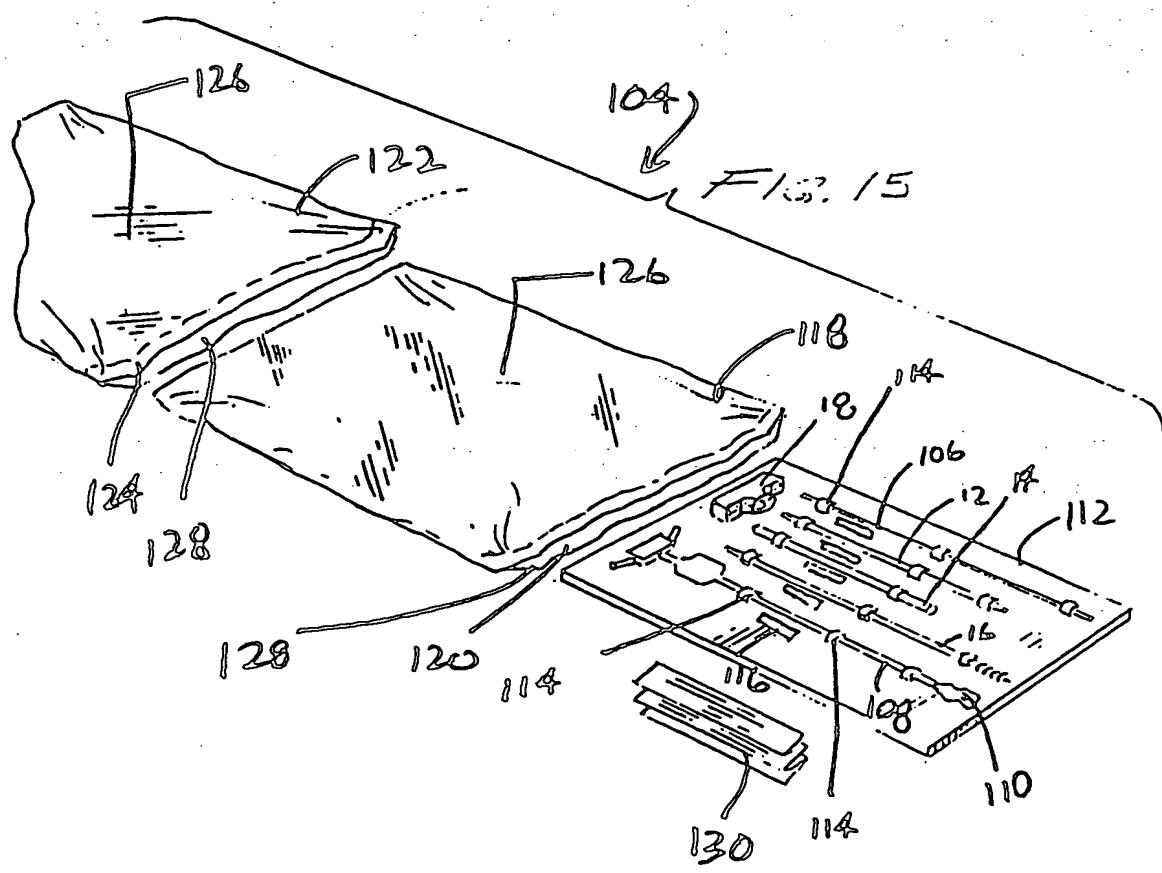
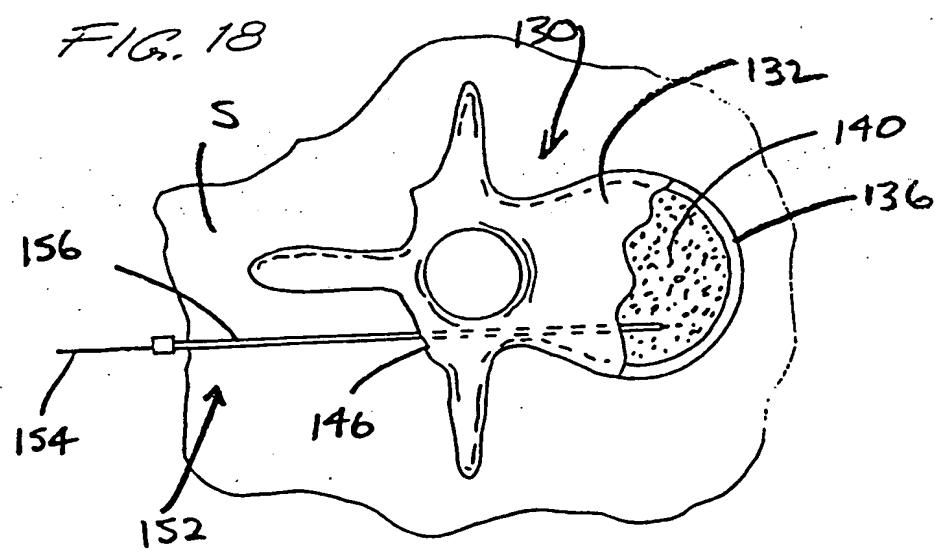
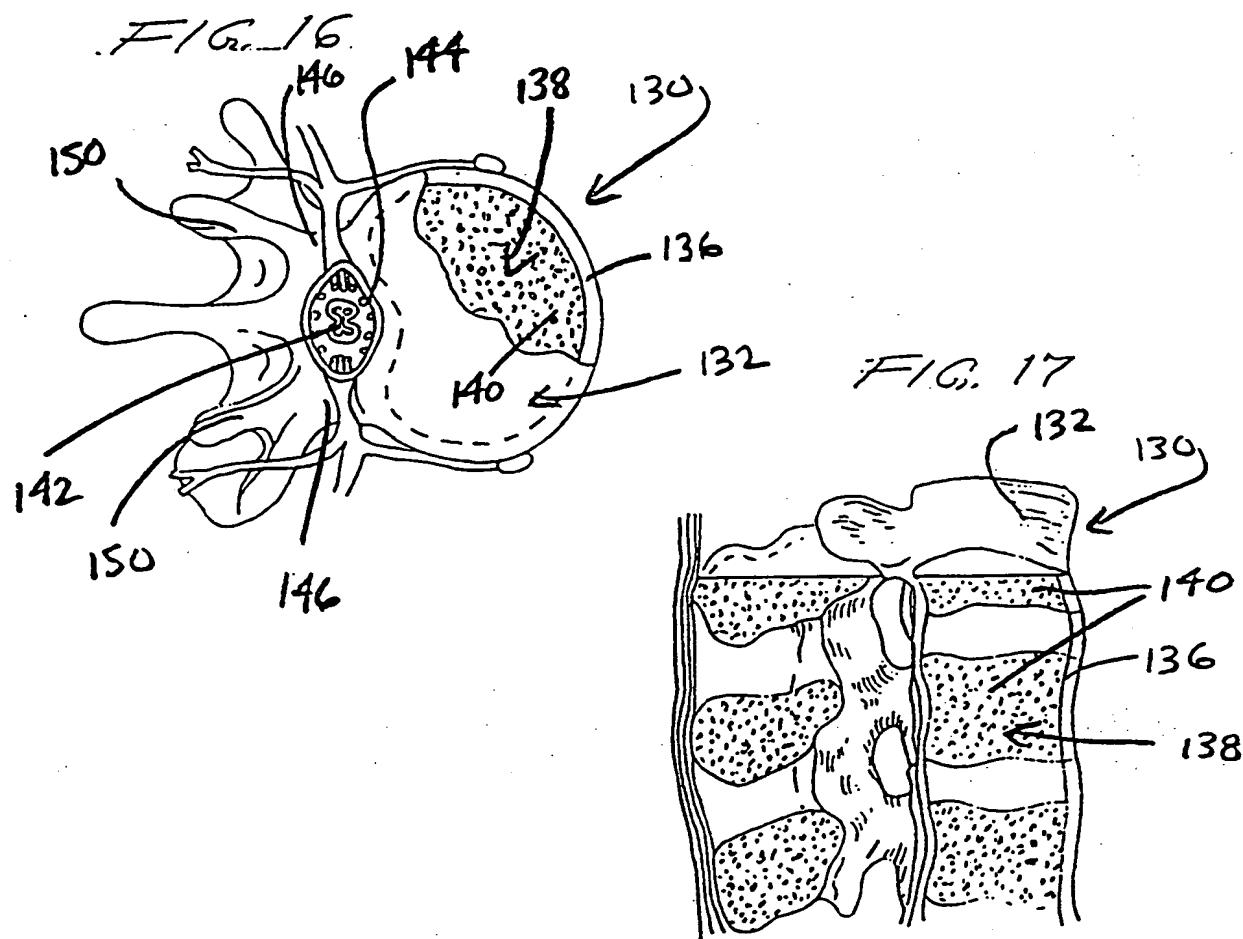
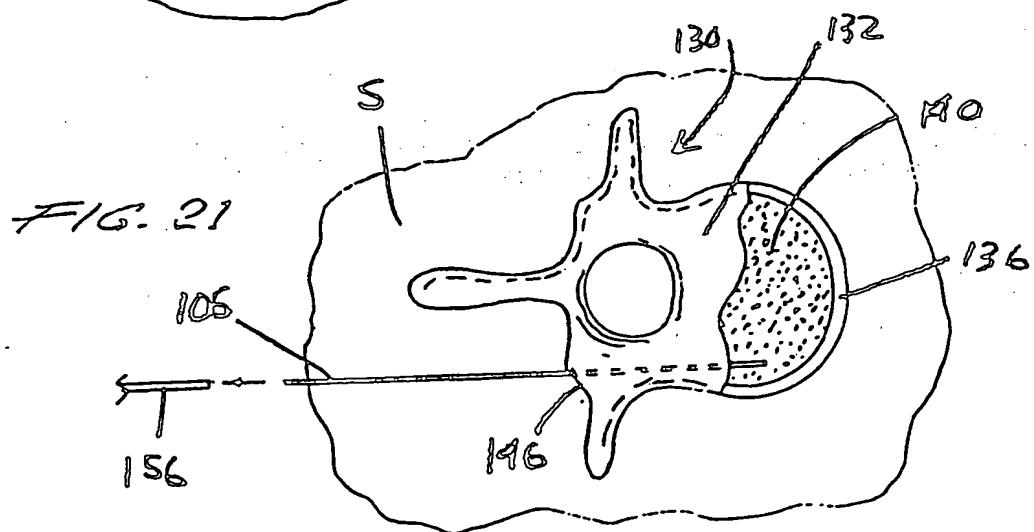
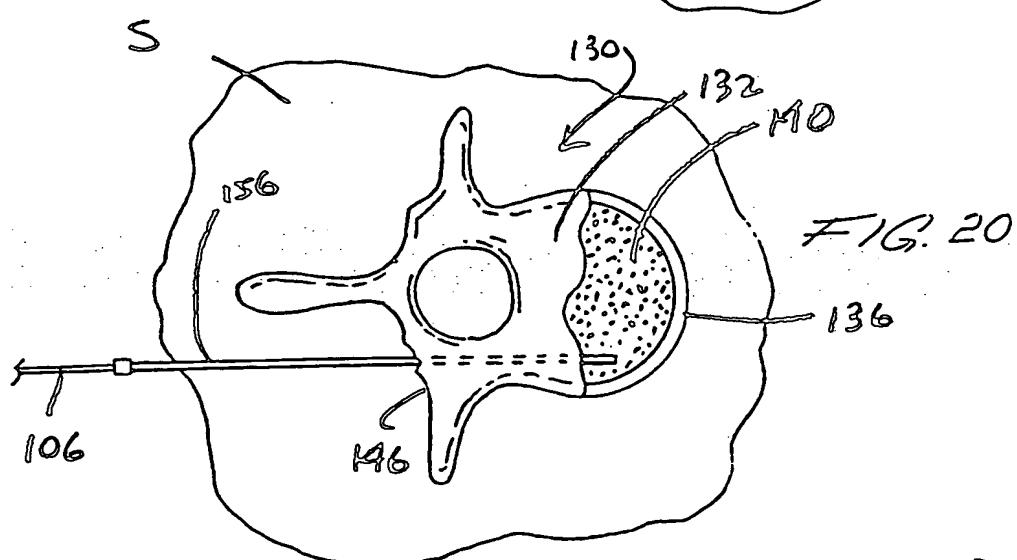
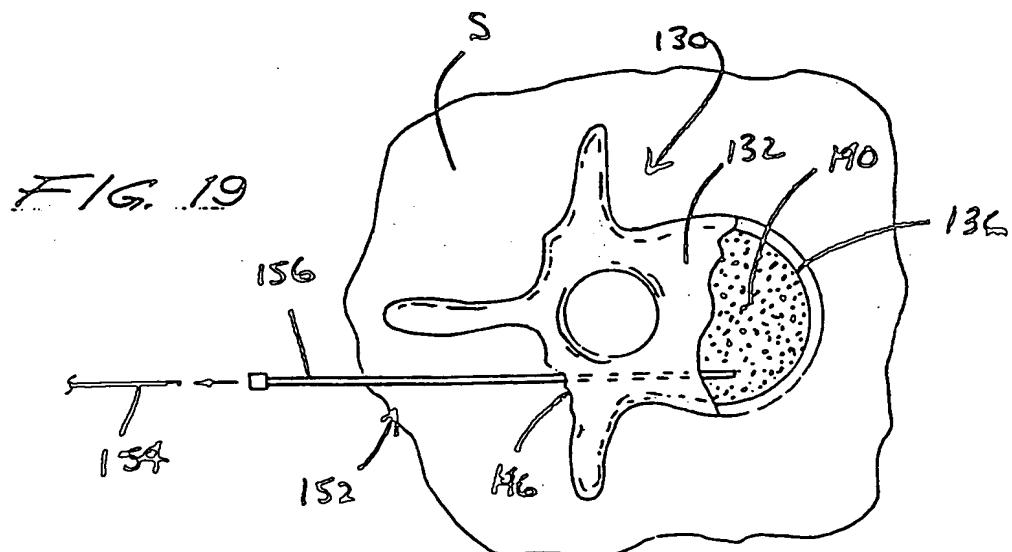
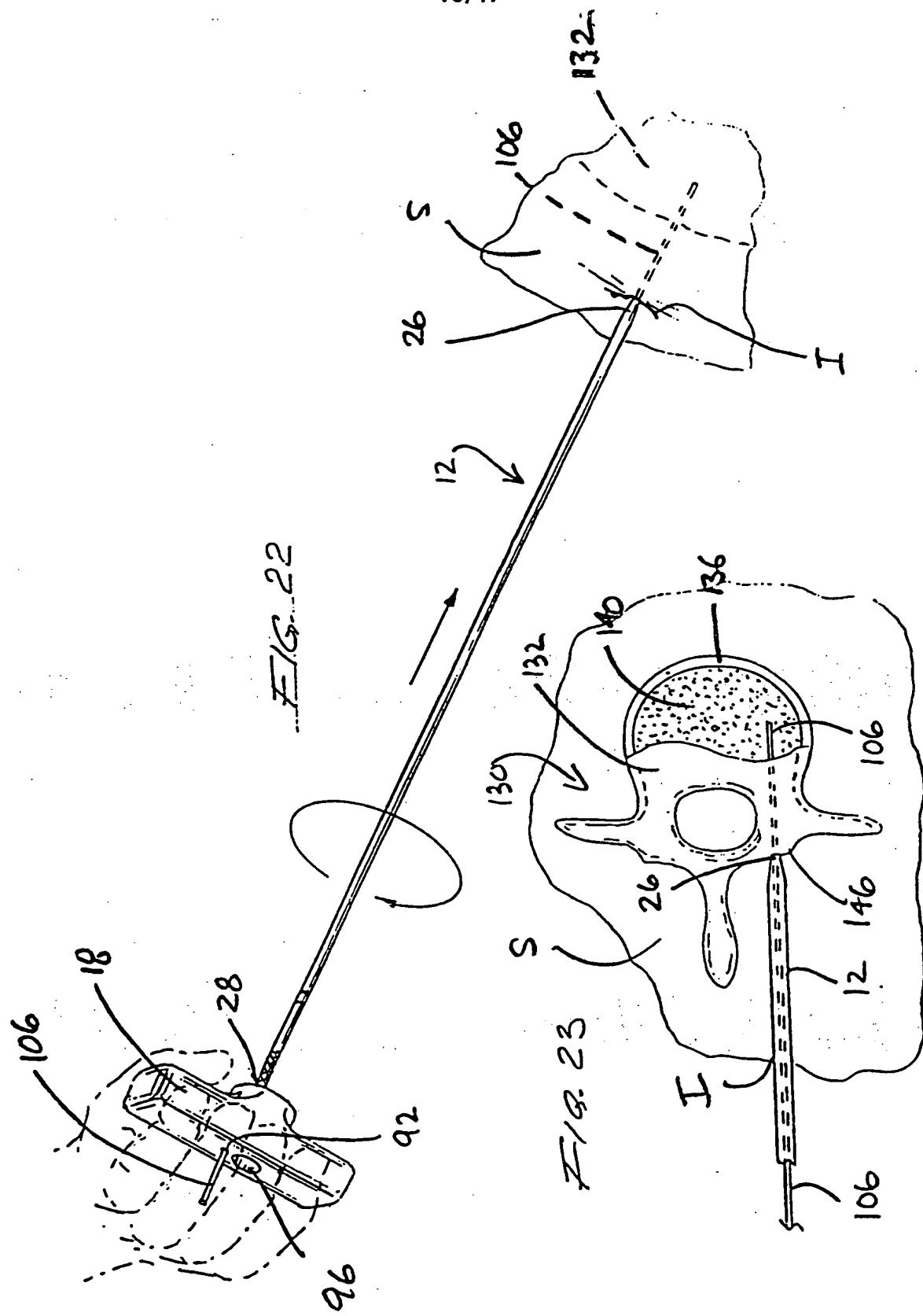


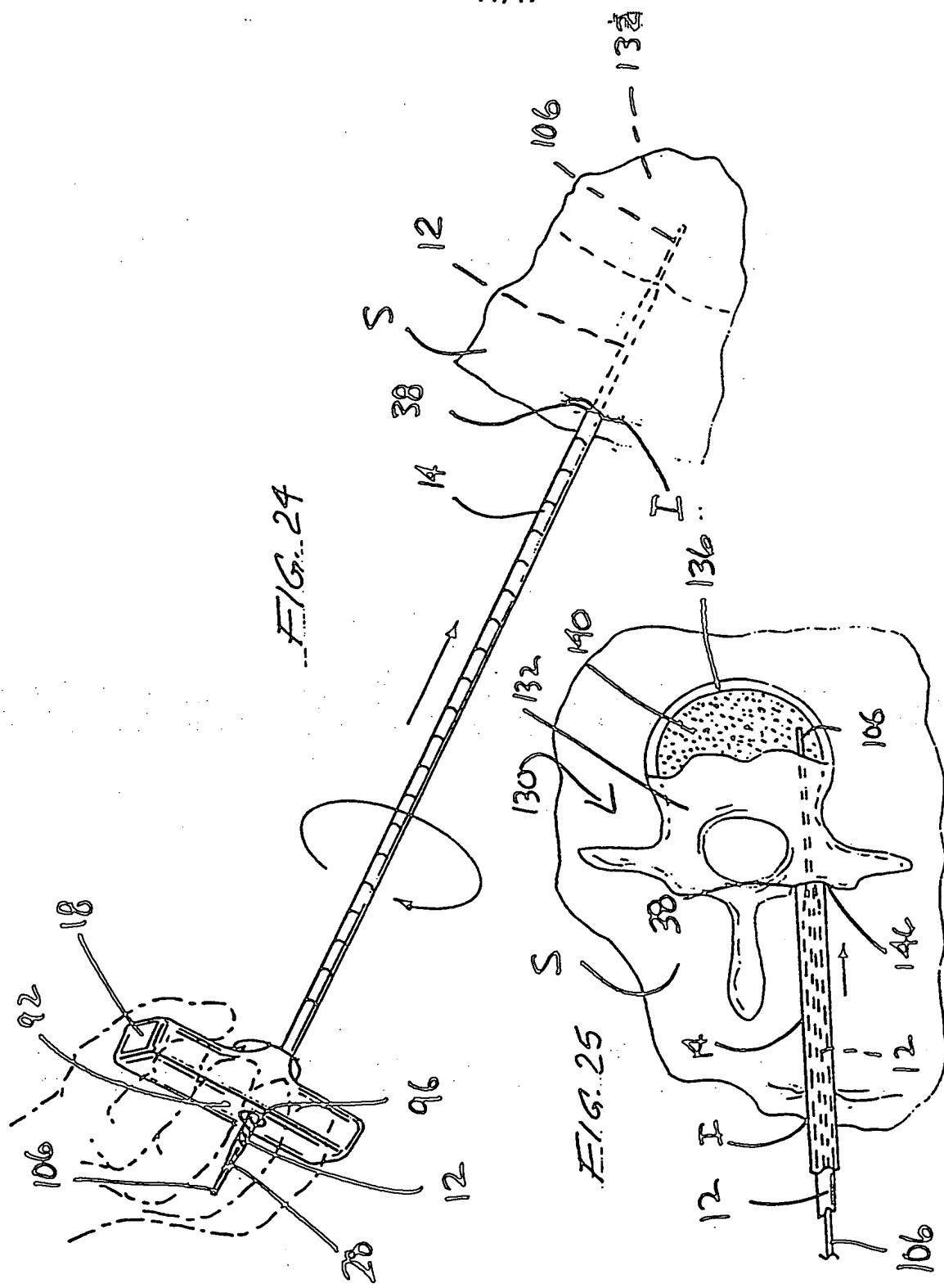
Fig. 15











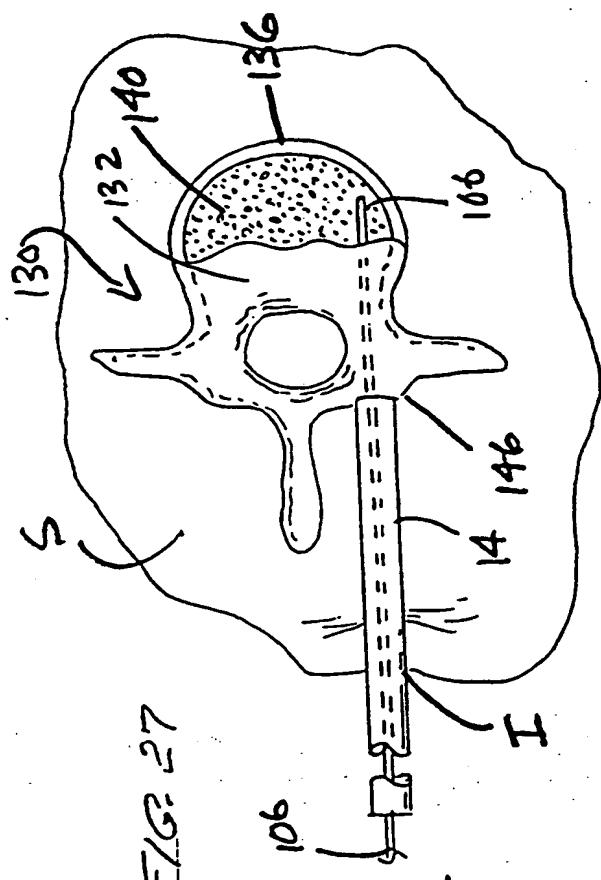


FIG. 27

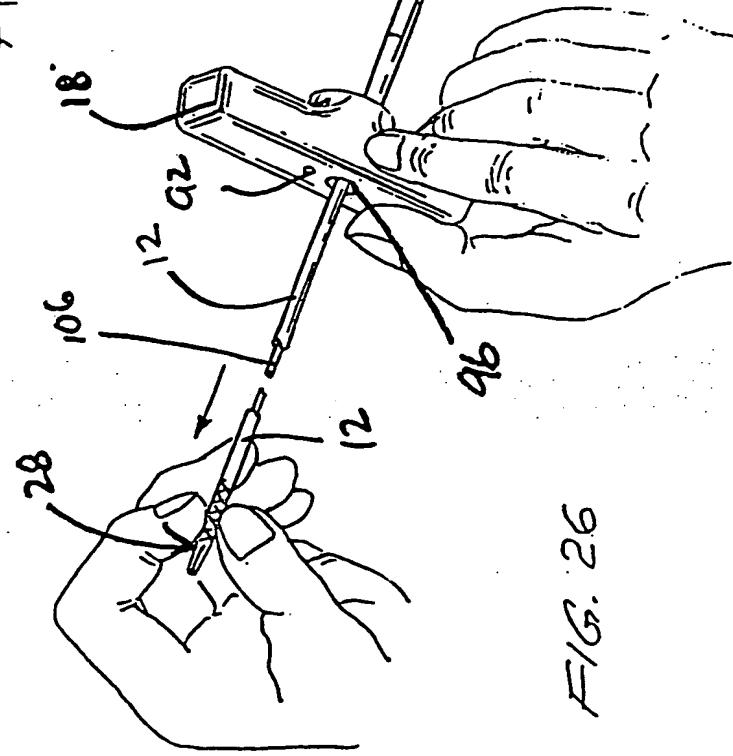
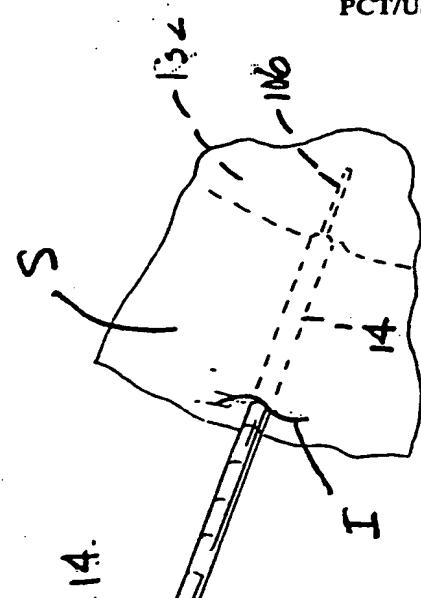
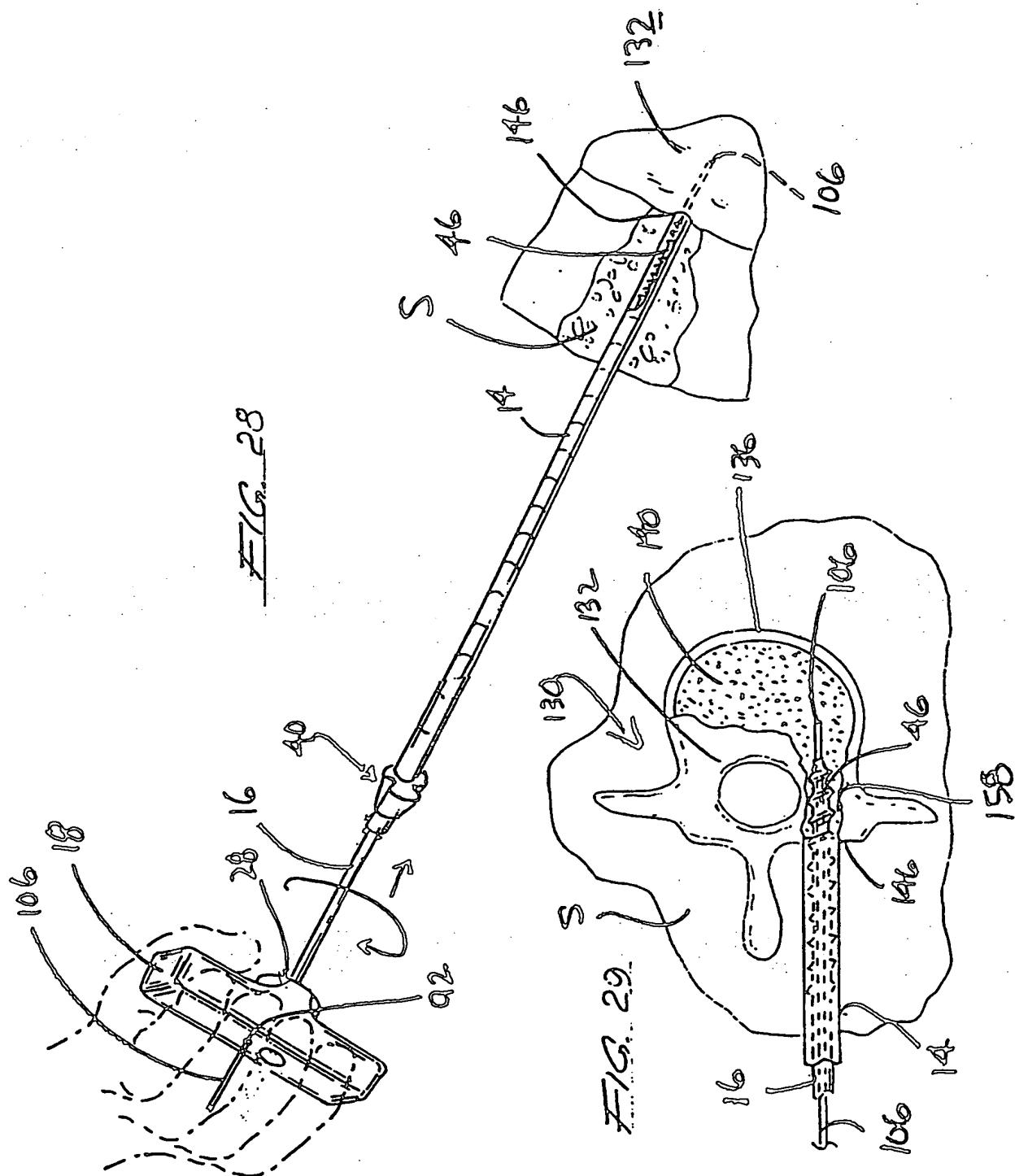
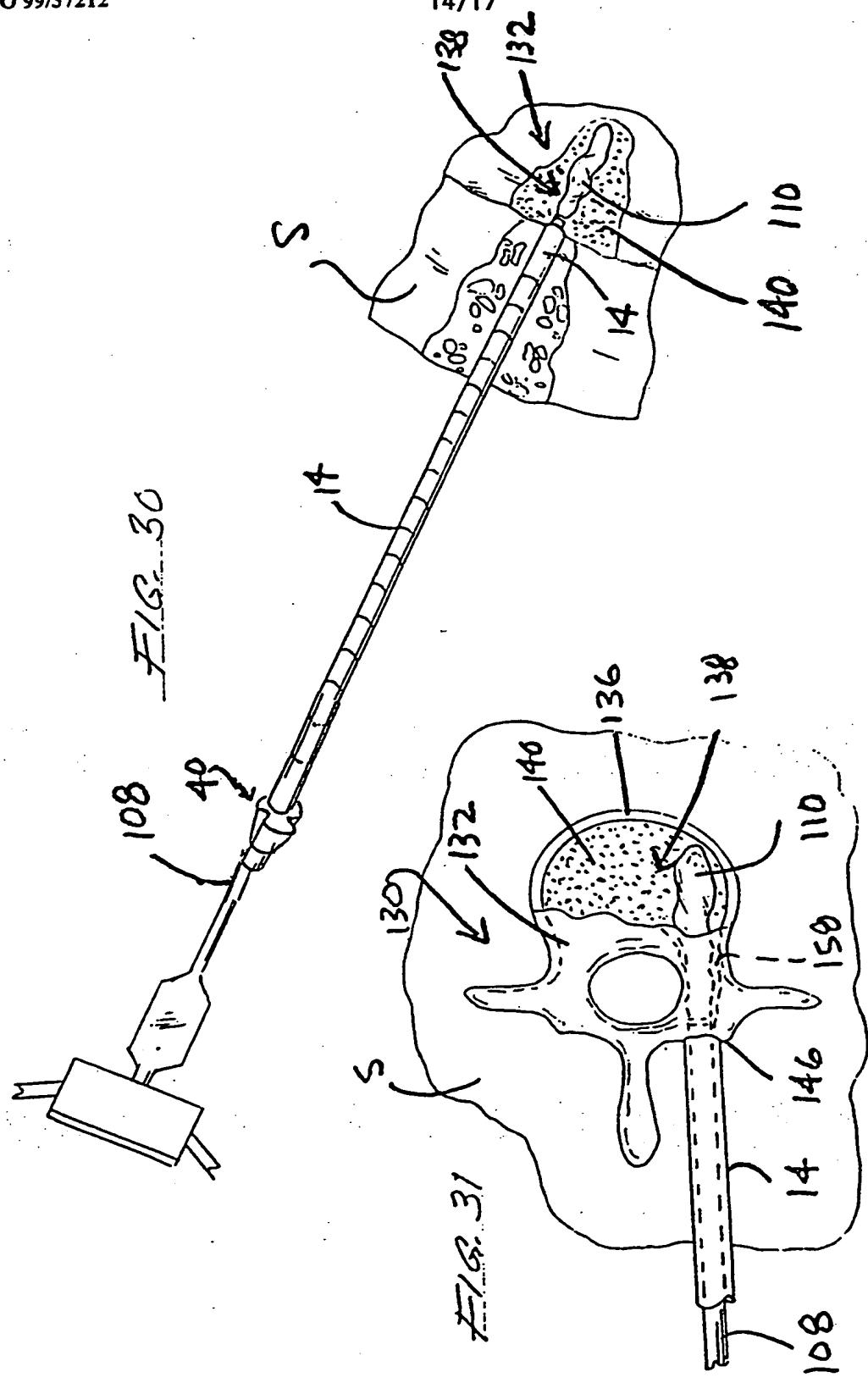


FIG. 26







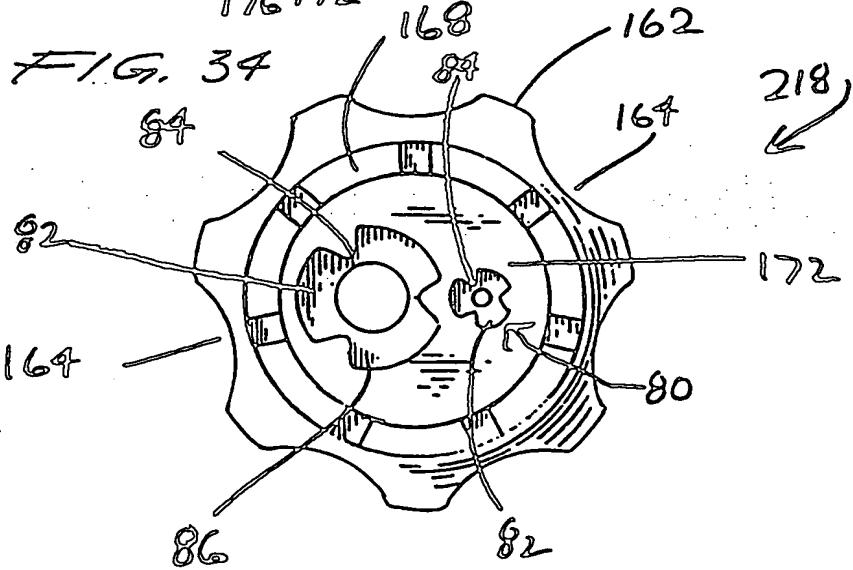
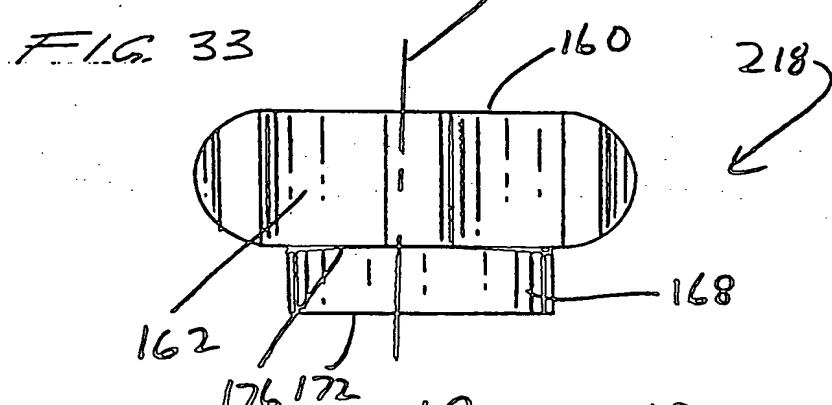
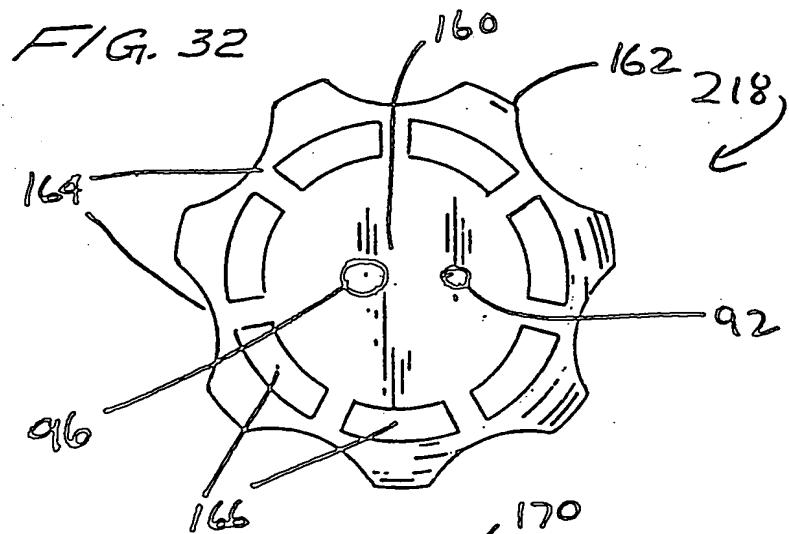


FIG. 35

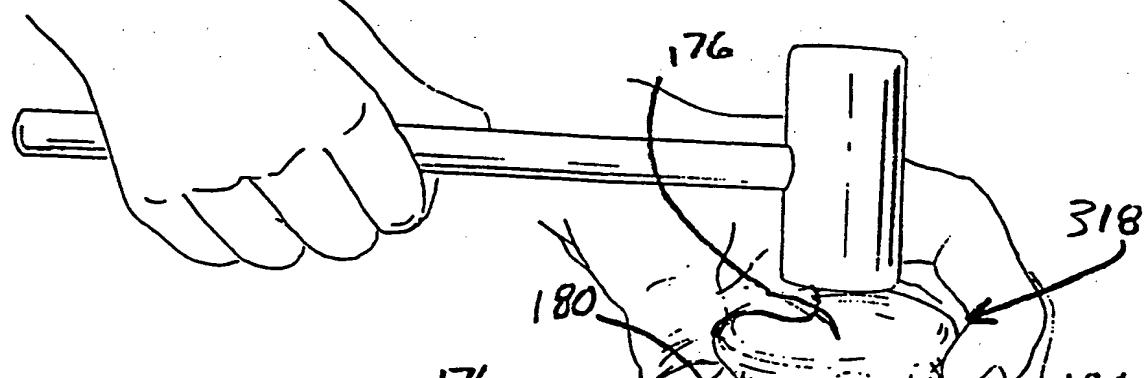


FIG. 36

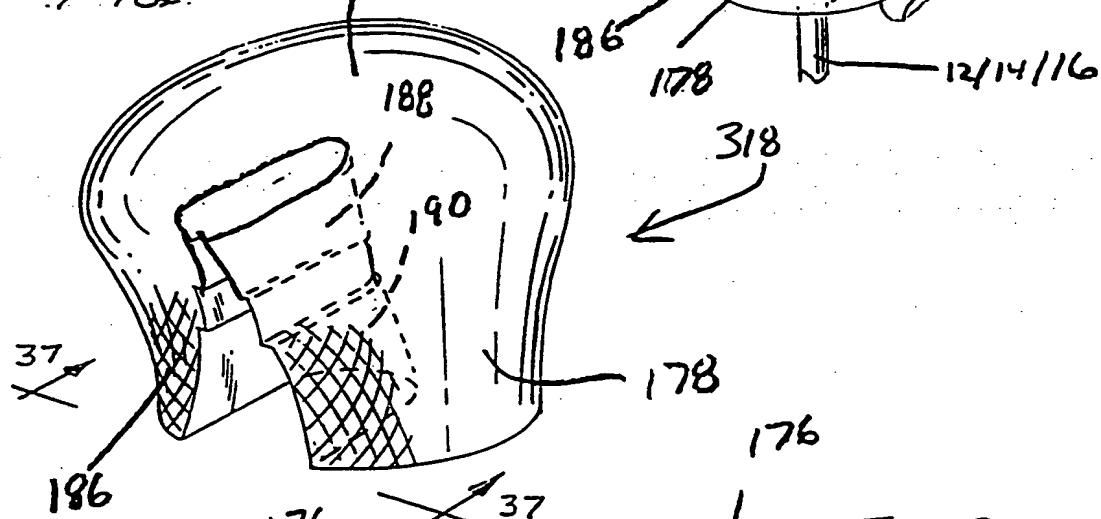


FIG. 37

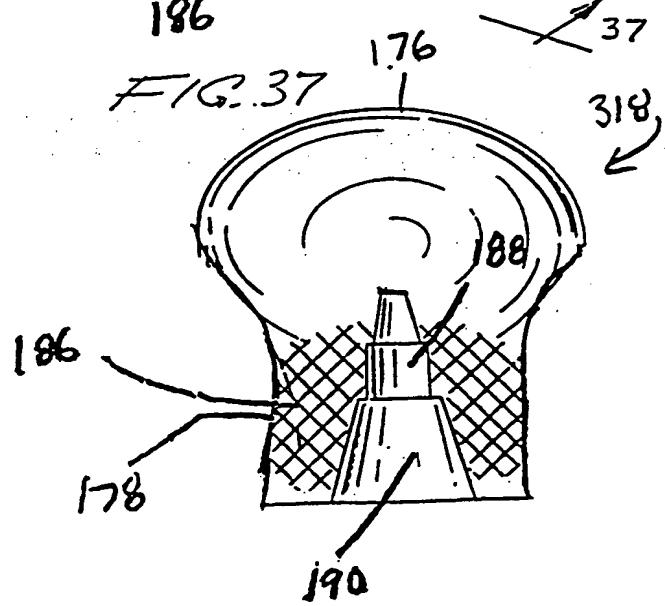
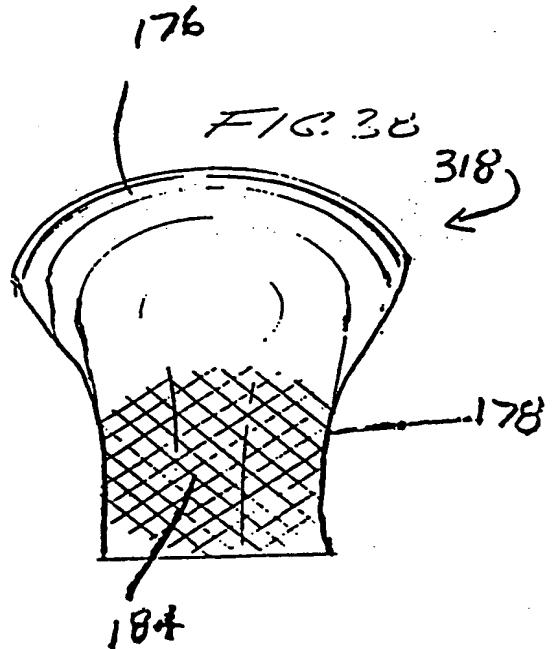
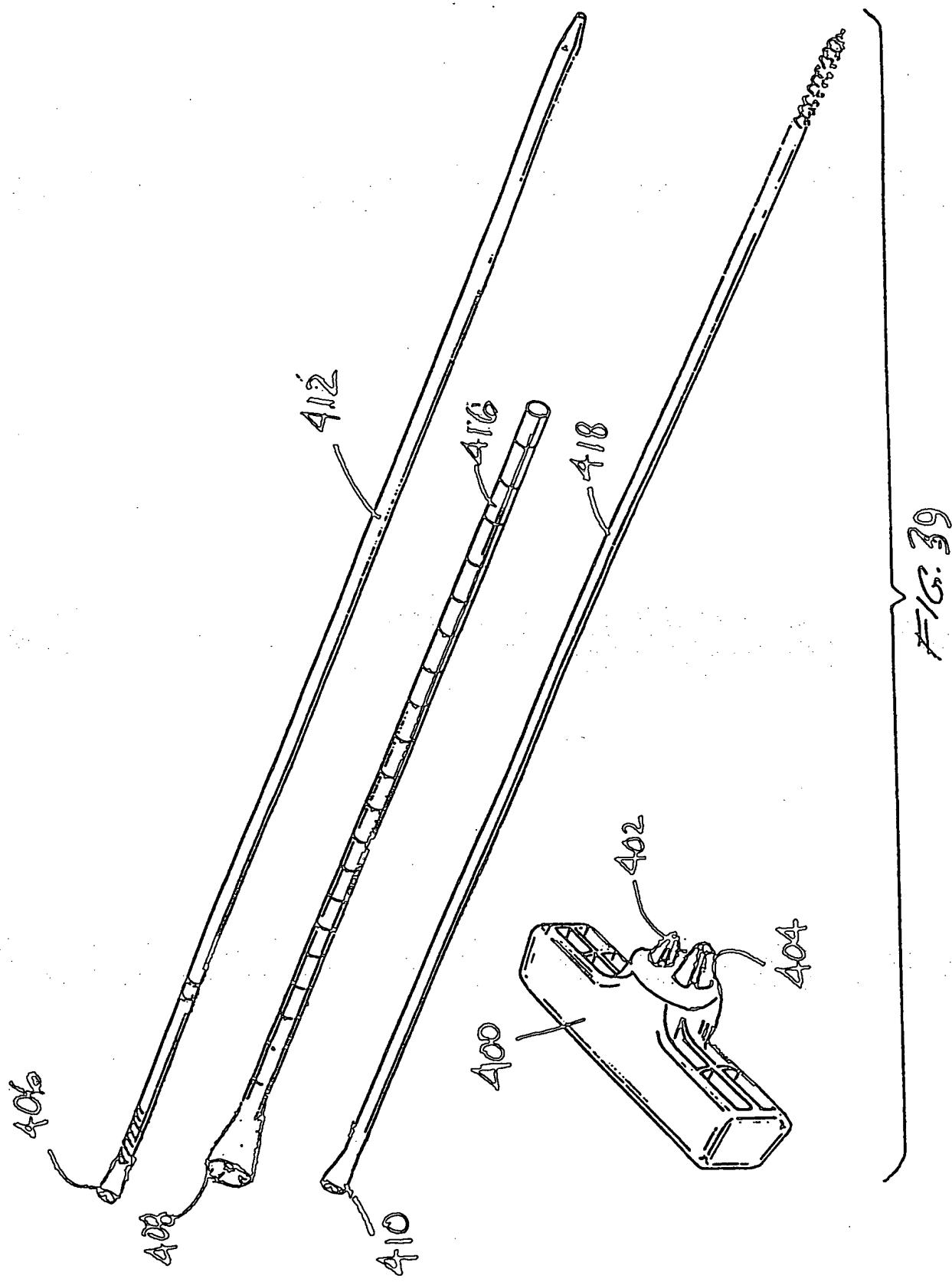


FIG. 38



17/17



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/01267

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61B 10/00

US CL : 600/567

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 16/DIG. 19, DIG. 41; 206/210; 279/9.1, 143, 145; 600/567; 606/79, 80, 104

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS,
Search Terms: T-handle, socket, surgical, shaft, screw, drill, rod, shaped, grip, hand, sterilization, gas, ETO, wrap

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,262,676 A (JAMSHIDI) 21 April 1981, Figs. 1-3.	1-7, 9, 11, 13, 15, 17-19, 21-35
X ---	US 5,522,398 A (GOLDENBERG et al.) 04 June 1996, Figs. 1, 2, 3a-3e and 7.	1-7, 9, 11, 13, 15, 17, 20-39
Y		40-59
Y,P	US 5,762,639 A (GIBBS) 09 June 1998, Fig. 7C.	43
Y	US 5,423,824 A (AKERFELDT et al.) 13 June 1995, col. 5 lines 6-26, and Figs. 1, 6 and 8.	54-59

 Further documents are listed in the continuation of Box C. See patent family annex.

• Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
• "A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
• "E" earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
• "L" document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Z"	document member of the same patent family
• "O" document referring to an oral disclosure, use, exhibition or other means		
• "P" document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

15 MARCH 1999

Date of mailing of the international search report

20 APR 1999

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

JULIAN W. WOO

Telephone No. (703) 308-0421

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/01267

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category ^a	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,480,166 A (MILSOP) 02 January 1996, whole document.	1-59
A	US 5,178,267 A (GRABENKORT et al.) 12 January 1993, whole document.	40-59

Form PCT/ISA/210 (continuation of second sheet)(July 1992) □